UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE AMARIN CORPORATION PLC, SECURITIES LITIGATION	Civil Action No. 13-cv-06663 (FLW)(TJB) JURY TRIAL DEMANDED

SECOND CONSOLIDATED AND AMENDED CLASS ACTION COMPLAINT

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GLOSSARY OF DEFINED TERMS

Defined Term	Definition
ACCORD-LIPID trial…….	The Food & Drug Administration ("FDA"), in 2008, approved Tripilix, a fenofibrate marketed by Abbott Laboratories, for treatment of high density lipoprotein cholesterol (HDL-C), low density lipoprotein cholesterol (LDL-C), and triglycerides (TGs). HDL-C, LDL-C, and TGs are also known as lipids. Tripilix was approved based on a 12-week phase III study that demonstrated efficacy in treating HDL, LDL, and TGs when co-administered with a statin already on optimal therapy. The Action to Control Cardiovascular Risk in Diabetes (ACCORD) long-term, multi-year clinical trial that enrolled more than 10,000 patients was an outcomes study that tested the hypothesis that reducing LDL-C and TGs, and increasing HDL, when co-administered with a statin already on optimal therapy, would lead to fewer major adverse cardiac events ("MACE"). The ACCORD outcomes study was publicly released in March 2010 (prior to the beginning of the Class Period). ACCORD failed to prove efficacy of Tripilix based on the long-term cardiac study, notwithstanding the reduction in lipid markers.
AIM-HIGH trial……..	The AIM-HIGH study was a long-term outcomes study designed to test the hypothesis that patients with atherosclerotic cardiovascular (CV) disease optimally treated on a statin but with residual atherogenic dyslipidemia (low high-density lipoprotein cholesterol [HDL-C] and high triglycerides) would benefit from addition of niacin with fewer CV events compared with placebo. Statin monotherapy trials have found 25%-35% CV risk reduction relative to placebo, leaving significant residual risk. Patients with atherogenic dyslipidemia have substantially increased CV risk. Participants were men and women with established CV disease and atherogenic dyslipidemia. All participants received a statin at a dose sufficient to maintain LDL-C 40-80 milligram per deciliter ("mg/dL," the unit used to measure the concentration of substances in the blood). Participants were randomized to extended-release niacin or matching placebo. Previously, niacin had been approved by the FDA based only on surrogate endpoints. AIM-HIGH was intended to test the hypothesis that a reduction in lipids would result in a long-term survival benefit. The primary end point was time to occurrence of the first of the following: coronary heart disease death, nonfatal myocardial infarction, ischemic stroke, hospitalization for acute coronary syndrome, or symptom-driven coronary or

	cerebral revascularization. Announcement was made on May 26, 2011 that the AIM-HIGH outcomes study was discontinued because there was no incremental clinical benefit from the addition of niacin to statin therapy during a 36-month follow-up period.
ANCHOR trial…….	ANCHOR was a 12-week clinical trial in which 702 patients with mixed dyslipidemia (two or more lipid disorders) on optimized background statin therapy for LDL-C were randomized to placebo (mineral oil) or Vascepa, with both co-administered with a statin. The primary and secondary endpoints of ANCHOR were the reduction of TGs without increasing LDL-C ("bad cholesterol") levels. The reduction of TGs in a short-term trial was considered a surrogate endpoint and is distinguished from a long-term outcomes trial where the primary endpoint is a survival benefit. Tests such as ANCHOR, which are based on surrogate endpoints, are based on a hypothesis (which may or may not be true) that the reduction of TGs caused by the add-on of Vascepa when co-administered with a statin on optimal therapy would lead to fewer MACEs.
HDL ("Good") Cholesterol (HDL-C)……	HDL cholesterol is considered "good" cholesterol because it helps remove LDL "bad" cholesterol from the arteries. Experts theorize that HDL-C acts as a scavenger, carrying LDL cholesterol away from the arteries and back to the liver, where it is broken down and passed from the body. One-fourth to one-third of blood cholesterol is carried by HDL. A healthy level of HDL cholesterol may also protect against heart attack and stroke, while low levels of HDL cholesterol have been shown to increase the risk of heart disease.
Hypertriglyceridemia……..	A condition in which patients have severe or very high levels of triglycerides (≥500mg/dL) in the bloodstream.
JELIS trial……	The Japan Eicosapentaenoic acid (EPA) Lipid Intervention Study (JELIS) trial was a large-scale, prospective, randomized open-label trial of combined treatment with a statin and an omega-3 fatty acid, eicosapentaenoic acid (EPA). The patient population was exclusively Japanese and was two-thirds women. JELIS examined the clinical effectiveness of EPA oil (Vascepa) given as an additional treatment to patients taking statins for hypercholesterolemia. The announced results stated that the addition of EPA to statin therapy provided additional benefit in preventing MACEs, apparently through lipid-independent mechanisms. JELIS was distinct from the double-blind ANCHOR study in that JELIS was open-label (both participants and researchers knew which treatment was being administered). Consistent with the fact that JELIS was open-label, the primary endpoint that tested for efficacy – the treatment of angina – was considered a subjective endpoint. Moreover, in JELIS, patients were on low non-optimized doses of statin (as compared to ANCHOR, in which patients were on optimized medium to high doses) and had higher than customary baseline LDL-C readings

	compared to patients on current optimized statin therapy. Thus, JELIS did not answer the question whether treatment with Vascepa when co-administered with statin based on optimized therapy, resulted in an improved MACE outcome.
LDL ("Bad") Cholesterol (LDL-C)…….	LDL cholesterol is considered "bad" cholesterol because it contributes to plaque, a thick, hard deposit that can clog arteries and make them less flexible. This condition is known as atherosclerosis. If a blood clot forms and blocks a narrowed artery, a heart attack or stroke can result.
LOVAZA…….	LOVAZA is approved by the FDA as an adjunct to diet to reduce triglyceride (TG) levels in adult patients with severe (≥500 mg/dL) hypertriglyceridemia. LOVAZA was developed by Reliant Pharmaceuticals and is sold by GlaxoSmithKline. It is a competitive product to Vascepa and was approved by the FDA in 2004 for marketing to the same patient population (severe hypertriglyceridemia) as Vascepa for the MARINE indication.
MARINE trial……..	The MARINE trial was a Phase III clinical trial conducted in a patient population with very high TGs (≥ 500 mg/dL) with a primary endpoint of reduction in triglyceride levels and other lipid parameters without an increase in LDL-cholesterol. The MARINE results were published in the September 2011 issue of the American Journal of Cardiology. Vascepa was approved by the FDA for the MARINE indication on July 26, 2012. The MARINE study did not require co-administration with a statin.
Mixed Dyslipidemia……	Mixed Dyslipidemia is a condition characterized as high TGs (≥200 mg/dL and < 500 mg/dL) and high LDL-C. Amarin's theory behind the ANCHOR trial is that the use of Vascepa when co-administered with a statin at optimal therapy will reduce the levels of TGs without elevating the LDL-C. The 12-week ANCHOR study tested the efficacy of Vascepa in reducing TGs while not elevating LDL-C when co-administered with a statin but did not test the efficacy of Vascepa to reduce MACEs in a long term outcomes study.
REDUCE-IT……	The REDUCE-IT trial is Amarin's long-term prospective cardiovascular outcomes trial ("CVOT") in high-risk patients on statin therapy. The primary endpoint of this double-blind, prospective, placebo-controlled trial is to show that Vascepa co-administered with existing statin therapy can provide a significant reduction in MACE. REDUCE-IT was initiated in November 2011. Pursuant to Amarin's August 6, 2009 Special Protocol Agreement ("SPA") with the FDA, Amarin was required to enroll at least 50% of the patients in the REDUCE-IT study (approximately 4,000 patients) as a condition for filing of the ANCHOR supplemental new drug application ("sNDA"). The study is expected to complete in 2017. REDUCE-IT is a global study, and is expected to enroll over 60% of its patients from western countries, ensuring that study results are applicable to the North

	American patient population.
Statins……....	Statins are a class of drugs that work in the liver to prevent the formation of LDL (bad) cholesterol, thus lowering the amount of cholesterol circulating in the blood. Statins are most effective at lowering LDL (bad) cholesterol, but also have modest effects on lowering triglycerides (blood fats) and raising HDL (good) cholesterol.
Surrogate Endpoint……..	A surrogate endpoint is a biomarker intended to substitute for a clinical endpoint. A surrogate endpoint may predict clinical benefit (or harm, or lack of benefit) based on epidemiologic, therapeutic, pathophysiologic or other scientific evidence that can be relatively quickly and easily measured, and that are taken as being predictive of important clinical outcomes. They are often used when observation of clinical outcomes requires long follow-up.
Triglycerides (TGs)……	Triglycerides (TGs) are a type of fat used to store excess energy. High levels of triglycerides in the blood are associated with atherosclerosis (a disease in which plaque builds up in the arteries). Elevated triglycerides can be caused by overweight and obesity, physical inactivity, cigarette smoking, excess alcohol consumption and a diet very high in carbohydrates (more than 60 percent of total calories). Underlying diseases or genetic disorders are sometimes the cause of high triglycerides. People with high triglycerides often have a high total cholesterol level, including high (bad) LDL-C and low (good) HDL-C. Many people with heart disease or diabetes also have high triglyceride levels.
Outcomes Study……...	An outcomes study is a long-term study (commonly more than one year), involving a large patient population (commonly more than 1,000 patients), in a double-blinded study, to access the efficacy of a drug based on rare occurrences (such as major adverse cardiac events).
Vascepa……...	Vascepa (icosapent ethyl) is Amarin's primary drug. Vascepa has been approved by the FDA for use as an adjunct to diet to reduce triglyceride levels in adult patients with severe (≥500 mg/dL) hypertriglyceridemia (the MARINE indication).

1. Lead Plaintiff, James Reiss, by his attorneys, brings this action as a class action on behalf of himself and all other persons or entities who purchased American Depositary Shares (ADSs) of Amarin Corporation plc ("Amarin") on the open market, or pursuant to Registration Statements filed with the Securities and Exchange Commission, during the period from November 29, 2010 through October 16, 2013 (the "Class").

2. Lead Plaintiff alleges the following based upon personal knowledge as to himself and his own acts and upon information and belief as to all other matters. Lead Plaintiff's information and belief is based on, among other things, the independent investigation of his undersigned counsel. This investigation included, but was not limited to, a review and analysis of: (a) Amarin's public filings with the Securities and Exchange Commission (the "SEC"); (b) research reports by securities and financial analysts; (c) transcripts of Amarin's earnings conference calls and industry conferences; (d) other publicly available presentations by Amarin; (e) Amarin's press releases; (f) news and media reports concerning Amarin and other facts related to this action; (g) data reflecting the pricing and trading volume of Amarin ADS; (h) consultations with experts, and analyses of FDA practices and precedent with respect to the FDA drug approval regulatory process; (i) information obtained from former Amarin employees and other individuals with knowledge of the facts alleged; (j) declarations and exhibits filed by Amarin and the FDA in separate litigations commenced by Amarin against the FDA in the U.S. District Courts for the Southern District of New York (15-cv-03588) (the "NY Action") and the District of Columbia (14-cv-00324) (the "DC Action"); and (k) other publicly available material and data, including as identified herein.

I. INTRODUCTION

3. At a meeting with the FDA on July 14, 2008, Amarin requested whether the "design" of a twelve-week study of triglyceride lowering surrogate endpoints in patients already treated with statins was "adequate to provide the clinical efficacy data necessary to support the proposed [ANCHOR] Indication."

4. The FDA advised Amarin at that meeting that the FDA would not commit to approving ANCHOR based only on a surrogate end-point. Rather, the FDA told Amarin that (i) the FDA was "not aware of any prospective, controlled clinical trial date demonstrating that pharmacological reduction of non-HDL-C (or TG) with a second drug in patients with elevated TG levels at LDL goal on statin therapy significantly reduces the residual risk for CVD [cardio-vascular disease]", and that (ii) "three ongoing CVOTs [AIM-HIGH, ACCORD, and IMPROVE-IT] while not designed to address the specific gap in knowledge, will provide important information on the incremental benefit of adding a second lipid-active drug to statin therapy."

5. Accordingly, the FDA, at the July 14, 2008 meeting, informed Amarin that it would be required, as a condition to submitting a new drug application ("NDA") for the ANCHOR indication, "at a minimum," to submit the twelve-week ANCHOR study and initiate an appropriately-designed outcomes study such that approximately half of the patients were enrolled when the NDA is submitted.

6. Lead Plaintiff had alleged primarily in the Consolidated Class Action Complaint dated September 19, 2014 ("CAC") that because of the FDA's warnings at the July 14, 2008 meeting and because the AIM-HIGH and ACCORD trials were failures, defendants' public statements that "the results of an outcome study were not required for FDA approval of the ANCHOR indication" were materially false and misleading. Rather, defendants knew that the

FDA was unlikely to approve Vascepa for the ANCHOR indication based only on a twelve-week trial of surrogate endpoints, and was likely to require the results of the long-term REDUCE-IT Cardiovascular Outcomes Trial ("CVOT") prior to drug approval. The omitted facts with respect to the July 14, 2008 FDA meeting would have had actual significance to a reasonable investor and were necessary, in order to make defendants' public statements to investors during the Class Period, in light of the circumstances under which they were made, not misleading.

7. On June 29, 2015, this Court issued an Opinion and entered an Order dismissing plaintiff's CAC without prejudice. Dkt. Nos. 73 and 74.

8. The Court held that "none of Defendants' statements affirmatively characterized the importance of the outcomes study; Defendants are merely alleged to have stated, correctly, that the studies were not required to be completed in order for the ANCHOR indication process to continue." *See* also *id.* at 14, fn.19 ("Defendants merely stated that a long-term outcomes study, which was already underway, was not required to be completed for the ANCHOR indication, to be approved; that the completion of any other such studies underway would provide important information does not conflict with those statements."). *See* Opinion dated June 29, 2015 (Dkt. No. 73).

9. This Court also held that the CAC failed to plead with sufficient specificity that the named defendants, individuals who were not present at the July 14, 2008 meeting, were aware of the FDA's warnings at that meeting (reflected in meeting minutes) and were economically motivated to commit fraud. *See, e.g.*, slip op. at 33 ("Here, that the FDA expressed its opinion at one point that the results of the ACCORD and AIM-HIGH studies would be 'important information' with respect to the ANCHOR indication is not even a specific enough statement to qualify as a fact that was important to Amarin's business; even if it were, Plaintiff has not

adequately alleged that the individual defendants had knowledge of the FDA's comment. Thus, Plaintiff's allegation that Vascepa is Amarin's core business are insufficient to support a strong inference of scienter.")

10. The Court's dismissal, was without prejudice and with leave to amend. Pursuant to the Court's Order, Lead Plaintiff respectfully submits this Second Consolidated and Amended Class Action Complaint (the "SCAC"), containing the following amendments to the CAC:

a. The SCAC adds allegations based on declarations and exhibits in litigation filed by Amarin against the FDA in the NY Action. On May 7, 2015, Amarin brought litigation against the FDA in the Southern District of New York (Civil Action No. 1:15-cv-03588-PAE) alleging that the FDA violated Amarin's First Amendment rights to freedom of speech by restricting the factual content of information contained on the label for the MARINE indication. Primarily on June 23, 2015 and June 30, 2015, the FDA and Amarin filed documents in that action, on Amarin's motion for a preliminary injunction, providing substantial additional factual information with respect to Amarin's ANCHOR sNDA to approve Vascepa for the treatment of high TGs.

b. This regulatory record establishes that in an SPA dated July 6, 2009, the FDA informed Amarin that it would not commit to approve Vascepa for the ANCHOR indication, based only on the 12-week test of surrogate endpoints, and the commencement of the REDUCE-IT outcomes study, but that approval would be "a review issue." NY Docket No. 53-2. Subsequently, in a conference call conducted on April 14, 2011, the FDA told Amarin that "an Advisory Committee meeting was likely before the indication could <u>possibly</u> be granted." NY Docket No. 53-12 (at 2); emphasis added. Thereafter, in an SPA dated August 5, 2011, the FDA reiterated that it would not

commit to approve Vascepa for the ANCHOR indication, even if REDUCE-IT was substantially underway, but that approval would be a "review issue." NY Dkt. No. 53-5.

c. Amarin and defendant Ketchum acknowledged, in the correspondence submitted in the NY Action, that the July 2009 SPA reflected that the FDA "recognized substantial uncertainties around the connection between the potential effects of Vascepa … in the ANCHOR population and cardiovascular risk reduction." *See, e.g.,* Ketchum correspondence to the FDA dated February 27, 2014, NY Dkt. No. 64-5 at 5. Ketchum further acknowledged in a November 7, 2013 letter to the FDA that "[b]oth parties understood that the potential for CV risk reduction in an ANCHOR-like patient population could not be resolved until the ultimate outcome of the ongoing REDUCE-IT trial." NY Dkt. No. 64-1 at 47-48. Defendants failed to convey to investors during the class period the FDA's skepticism around the science reflected in Amarin's ANCHOR submission and that the scientific issue could only be settled by completion of the REDUCE-IT study.

d. Two of the most senior FDA officials in Washington (Dr. Curtis J. Rosebraugh and Dr. John K. Jenkins), who have personal knowledge of the facts at issue in this action and are uncontestable experts in FDA regulatory practices and whose findings are entitled to substantial deference, concur with plaintiff's allegations that Amarin acted in reckless disregard of known facts. Among other things, these FDA senior officials have stated in correspondence that Amarin's arguments that it was "unaware of how tenuous [the FDA's] confidence was in TG as a surrogate" is "difficult to accept after reviewing the regulatory record," and that the objective facts of Amarin's dealings with the FDA "indicates the fragile nature of the evidence supporting TG's hold onto surrogate status."

See correspondence from Curtis J. Rosebraugh to defendant Ketchum dated April 22, 2014, NY Dkt. No. 53-7, at 16. Dr. Rosebraugh refused to "give credibility to [Amarin's] assertions that these facts were minor and did not warrant importance or continued consideration on your part." *Id.* Dr. Jenkins similarly concluded that Amarin's conduct "defies logic." *See* correspondence from John K. Jenkins to defendant Ketchum dated September 11, 2014, NY Dkt. No. 53-11 at 7.

e. Plaintiff quotes and references the actual text of the July 14, 2008 FDA meeting Minutes. Those Minutes were not available to Lead Plaintiff at the time of filing the CAC. The Minutes were filed by defendants under seal in this Court as an exhibit on defendants' motion to dismiss the CAC. Those same Minutes were subsequently publicly filed by the FDA as NY Dkt. No. 56-1 to 56-4. Those Minutes confirm the strength of plaintiff's allegations and contain among other things material facts concerning the lack of comparability of JELIS to ANCHOR and REDUCE-IT. *See* ¶ 22, *infra*. The SAC also adds allegations from the Minutes with respect to mineral oil. *See* ¶ 105. Those Minutes are the official records of communications between Amarin and the FDA. Amarin itself has cited its reliance on those Minutes in litigation against the FDA in the DC Action. *See* ¶ 123.

f. The SCAC also contains additional allegations based on JELIS from Amarin's Form 10-K SEC filings, as well as allegations concerning the timing of the FDA's communications with Amarin with respect to mineral oil. *See* ¶¶ 104, 180, 238, and 409.

g. Whereas the CAC alleged primarily that defendants misrepresented and failed to disclose that the CVOT REDUCE-IT study was likely to be required to be completed

before the FDA would approve the ANCHOR indication, the SCAC adds more specific allegations that defendants misrepresented other facts, including that (i) TG-lowering studies were an accepted surrogate for long-term CV studies, and (ii) the failure to ACCORD and AIM-HIGH were positive developments for Amarin because they reduced competition. Each of those representations was materially false and misleading, and made with intent to defraud or reckless disregard for the truth. *See* ¶ 209.

h. The SCAC contains additional allegations with respect to the individual defendants' insider selling and emphasizes that Amarin itself was motivated to commit fraud to market their public offerings of securities that were essential for Amarin's financial viability. *See, e.g.*, ¶¶ 444-45, 449-53.

i. The SCAC adds allegations concerning Dr. Declan Doogan. Dr. Doogan, as Chief Medical Officer, attended the July 14, 2008 FDA meeting on Amarin's behalf and had actual knowledge that his and defendants' statements to investors prior to and during the Class Period were materially false. Dr. Doogan also acted as Amarin's Interim Chief Medical Officer prior to the Class Period. Plaintiff was not aware until defendants' filing of the July 14, 2008 FDA Minutes as an exhibit on the motion to dismiss the SCAC, that Dr. Doogan had attended that meeting, and therefore had actual knowledge of the falsity of defendants' statements. Dr. Doogan's knowledge and the information reflected in the Minutes is attributable to Amarin and the Individual Defendants under principles of corporate scienter and principal agent law. *See, e.g.*, ¶¶ 23, 24, 122, 124, 185, 190-92, 194-96, 214-15, 243, and 428.

11. These amendments demonstrate, among other things, that defendants' public statements that the results of a CV outcomes study was not required for FDA approval of the

ANCHOR indication, were materially false and misleading. Defendants' knew or were reckless in failing to know, by virtue of the July 14, 2008 Minutes, the March 14, 2011 teleconference with the FDA, and the July 6, 2009 and August 5, 2011 SPAs (and as confirmed by Dr. Ketchum in correspondence dated November 7, 2013 and February 27, 2014, and Drs. Rosebraugh and Jenkins in correspondence dated April 22, 2014 and September 11, 2014) that the results of a CV outcome study would be required for FDA approval of the ANCHOR indication.

II. SUMMARY OF THE ACTION

12. This action arises out of the Defendants' fraudulent scheme to improperly inflate the stock price of Amarin to enable the Company to raise over $226 million in new equity investments in two public stock offerings and to allow insiders to reap over $15 million in illegal profits on insider sales.

13. Public investors, on the other hand, suffered ruinous damages as Amarin's stock price plummeted from a high of $19.50 on May 27, 2011 to $2.01 per share the day after the end of the Class Period (October 17, 2013).

14. Defendants misrepresented facts to investors in public statements that Defendants knew to be untrue by virtue of contradictory private written and oral communications with the FDA.

15. Amarin is a test-phase pharmaceutical company. Amarin's lead product is Vascepa.

16. During the period from November 29, 2010 through October 16, 2013 (the "Class Period"), Amarin sought FDA approval to market Vascepa, based on a 12-week trial (the "ANCHOR study"), to treat patients with high trigylceride levels ("TGs") (≥200 mg/dL and

<500 mg/dL) when co-administered with a statin (the "ANCHOR indication").

17. Moreover, no drug is approved by the FDA for the ANCHOR indication, whereas other drugs were approved for MARINE.

18. Amarin's ANCHOR study was based on a hypothesis that reducing TGs in patients, when co-administered with a statin, would lead to a statistically significant reduction in major adverse cardiac events (MACE).

19. At a meeting with the FDA on July 14, 2008, Amarin asked if the FDA agreed "that the design of [the ANCHOR STUDY] is adequate to provide the clinical efficacy data necessary to support the proposed indication."

20. At that meeting, the FDA expressed reservations to Amarin about approving Vascepa based only on the 12-week ANCHOR surrogate end-point trial. Specifically, according to the Minutes of that meeting, the FDA informed Amarin that "we are not aware of any prospective, controlled trial data demonstrating that pharmacological reduction of non-HDL-C (or TG) with a second drug in patients with elevated TG Levels at LDL goal on statin therapy significantly reduces the residual risk of CVD." The FDA further advised Amarin at that meeting that "[t]he AIM-HIGH, ACCORD and IMPROVE-IT studies, while not designed to address the specific gap in knowledge, will provide important information on the incremental benefit of adding a second lipid-active drug to statin therapy." NY Dkt. No. 56-2 at 8.

21. The FDA further FDA further advised Amarin at the July 14, 2008 meeting that if it were to pursue the ANCHOR study that the REDUCE-IT long-term CVOT would have to be well underway (*i.e.*, approximately half of the patients enrolled when the sNDA is submitted):

> [B]efore we would entertain granting Ethyl-EPA an indication as add-on to statin therapy in patients with elevated TG levels, Amarin would at a minimum

> have to provide us with the results from a 12-week study similar to what you have proposed with Study B, and you would have to initiate an appropriately-designed cardiovascular outcomes study such that the trial was well under way at the time we reviewed the results from Study B.
>
> * * *
>
> In response to a question from the firm, the agency said that in order to consider granting an indication for add on therapy with statins, there must be an outcomes trial in process with approximately half of the patients enrolled when the NDA is submitted. Documentation as to enrollment would need to be included in the submitted NDA. [NY Dkt. No. 56-3 at 9.]

22. The FDA also informed Amarin at that meeting that it disagreed with Amarin's statement that "JELIS supports on indication for Ethyl-EPA add-on therapy to a statin in patients at LDL goal …:"

> First, the study was conducted in a Japanese population which is very different in terms of fish intake and cardiac event rate. Second, JELIS used a low statin dose (5 mg simvastatin and 10 mg pravastatin) rather than the maximum tolerated doses of more potent statins with EPA added-on to patients with persistently high TG levels. Third, the baseline levels of TG were essentially "normal and the changes in lipid parameters between treatment groups were so small that JELIS examined the non-lipid-altering effects of EPA on cardiovascular risk. [NY Dkt. No. 56-3, at 9].

23. Two senior officers of Amarin (Declan Doogan and Mehr Manku) and four Amarin consultants, were present at the July 2008 FDA meeting and their knowledge (gained within the scope of their employment) is attributable to Amarin under principal-agent principles.

24. Amarin's principal representative at the July 2008 FDA meeting, Declan Doogan, remained an officer of Amarin throughout the Class Period, in which Amarin and its senior officers continued to perpetuate the fraud on investors. Doogan has acted in various senior officer capacities for Amarin, including as Chief Medical Officer and Interim Chief Executive Officer. Doogan has acted as a principal spokesperson for Amarin on investor

conference calls, in press releases, and at investor conferences, and presented the ANCHOR efficacy data at the October 16, 2013 Advisory Committee Meeting.

25. Amarin's ANCHOR sNDA was required to be supported by substantial scientific evidence. By virtue of the July 14, 2008 meeting, Amarin had actual knowledge or acted in reckless disregard of the fact that if the AIM-HIGH, ACCORD, or IMPROVE-IT outcome studies (which were then underway) failed to demonstrate a survival benefit, the FDA was almost certain not to approve Vascepa based only on ANCHOR -- a 12-week phase III trial that enrolled 702 patients to test surrogate endpoints (primarily reduction of TGs). *Id.*

26. Subsequently, in March, 2009, Amarin submitted the ANCHOR protocol to the FDA and requested that the FDA enter into a Special Protocol Agreement providing that if the Anchor trial achieved its endpoints, the FDA would approve Vascepa to treat patients with high TGs.

27. On July 6, 2009, the FDA entered into an SPA with Amarin that unequivocally stated that notwithstanding whether the ANCHOR protocol achieved its endpoints, (i) the CVOT REDUCE-IT study would have to be 50% enrolled before the FDA would consider the ANCHOR sNDA, and (ii) that FDA approval of Vascepa for treatment of high TGs would be a "review' issue.

28. Amarin and defendant Ketchum have acknowledged in the NY Action that Amarin recognized by virtue of the July 14, 2008 meeting and the July 6, 2009 SPA the FDA's "substantial uncertainties" around the science supporting TG as a surrogate for CV risk. *See* Ketchum correspondence to the FDA dated February 27, 2014, NY Dkt. No. 64-5 at 5.

29. Although the three named individual defendants (Zakrzrewski, Ketchum, and Thero) were not officers of Amarin at the time of the July 14, 2008 meeting or July 6, 2009

SPA, they have at all times, in their public statements and in private communications with the FDA, held themselves out as having complete knowledge of Amarin's interactions with the FDA, and have never disclaimed knowledge or responsibility for having knowledge of the essential facts of Amarin's communications with the FDA.

30. During 2009 -2010, Amarin conducted the ANCHOR study, which was a 12-week Phase III clinical trial of 702 patients to determine if administration of Vascepa to the patient population already optimized on statin therapy reduced TGs.

31. In a telephone conference conducted with the FDA on March 14, 2011, Amarin was informed that prior to approval of the ANCHOR study "an Advisory Committee was likely before the indication could possibly be granted." NY Dkt. 53-12 at 2.

32. On August 5, 2011, the FDA entered into a separate Special Protocol Agreement with Amarin. *See* NY Dkt. No. 53-5 at 2. There, Amarin sought the FDA's agreement, that the "design and size" of the CVOT REDUCE-IT study, "prior to completion, will support the indication (to be applied for with adequate results from [the ANCHOR] study … and approximately 50% enrollment in REDUCE-IT."

33. As with the July 6, 2009 SPA, the FDA answered (in essence) "no" – and that "[t]he approvability of the indication will be a review issue."

34. Zakrzewski and Thero were then employed by Amarin and had actual knowledge, or were reckless in failing to know, as of August 5, 2011, that approval of the ANCHOR indication, notwithstanding ANCHOR's ability to achieve efficacy based on surrogate endpoints, was a "review" issue and was likely to require completion of the REDUCE-IT trial particularly in light of the failure of ACCORD and AIM-HIGH.

35. Amarin's future profitability throughout the Class Period was dependent on

obtaining FDA approval to market Vascepa based on the ANCHOR study without first being required to conduct a long-term outcomes study.

36. During the Class Period, defendants estimated that the potential patient population for the ANCHOR indication was 36 million patients. Although the MARINE indication was approved by the FDA, that population was only four million patients.

37. Both ACCORD-Lipid and AIM-HIGH proved unsuccessful, with the test results for ACCORD-Lipid being announced in March 2010 and the discontinuation of AIM-HIGH being announced in May 2011.

38. Notwithstanding Defendants' actual knowledge, initially, (i) of the lack of substantial scientific evidence supporting the ANCHOR indication based only on surrogate endpoints, (ii) that the likelihood of FDA approval based on the ANCHOR alone would be influenced by the success of the ACCORD-Lipid and AIM-HIGH trials, (iii) that the July 6, 2009 and August 5, 2011 SPAs had not committed the FDA to approve Vascepa for the ANCHOR indication even if the ANCHOR trial achieved its surrogate endpoints, (iv) that they were informed by the FDA in March 2011 that approval of ANCHOR would require an advisory committee and was merely "possible," and subsequently, (v) that the ACCORD-Lipid and AIM-HIGH trials had been unsuccessful, defendants intentionally failed to inform investors of the connections drawn by the FDA among the three studies (ANCHOR, ACCORD, and AIM-HIGH), and the FDA's "uncertainty around the science supporting TG as a surrogate for CV risk," and the FDA's statement that AIM-HIGH and ACCORD would provide "important information on the incremental benefit of a second lipid active drug to statin therapy."

39. Rather, Defendants misrepresented facts with respect to the likelihood of obtaining FDA approval for the ANCHOR indication without REDUCE-IT to induce Class

Members to make in excess of $226 million of investments in Amarin securities through two secondary offerings – on January 6, 2011 – 13.8 million ADS at $7.60 per ADS, and on July 10, 2013 – 21.7 million ADS at $5.60 per ADS. Among defendants misrepresentations were that: (i) the long-term REDUCE-IT study was not required for approval of the ANCHOR indication when defendants knew it was almost certain to be required, (ii) the failure of AIM-HIGH and ACCORD were a positive for Amarin because it would reduce competition for MARINE and ANCHOR, when defendants knew it made it less likely that the FDA would improve the ANCHOR indication prior to completion of the CVOT REDUCE-IT study, and (iii) use of TG reduction as a surrogate marker for MACE was well established, when the FDA had advised Amarin unequivocally that it was "not aware of any prospective, controlled trial data demonstrating that [reduction of TGs] significantly reduces the residual of CVD."

40. Defendants were motivated to commit the fraud because they knew that Amarin was required to raise cash in public offerings to conduct the long-term REDUCE-IT study and that investors would be unwilling to buy Amarin ADSs in these public offerings if they knew that Amarin was required to conduct the long-term REDUCE-IT study at an expense in excess of $100 million to get FDA approval.

41. The long-term REDUCE-IT study introduced an element of cost, risk, and delay that would have been unacceptable to public investors.

42. Reflecting its financial motive to misrepresent facts, Amarin, in 2014 asked the FDA to approve the ANCHOR indication or at least add information concerning the results of the ANCHOR trial to the MARINE label, because Amarin needed additional revenue from Vascepa sales to complete the REDUCE-IT trial, notwithstanding the lack of substantial scientific proof that Vascepa was medically effective in reducing MACE.

43. The FDA, in response, chided Amarin for placing its profit motive ahead of science. *See* Letter from Dr. Rosebraugh to Dr. Ketchum dated April 22, 2014 at 18 (NY Dkt. No. 53-7) ("approval decisions are based on the statutory standard, not on whether an approval will provide a company with financial revenue.").

44. Defendants also misrepresented facts concerning the JELIS study conducted in Japan and the use of mineral oil as a placebo in the ANCHOR study.

45. Accordingly, and unbeknownst to the investing public, Amarin securities traded at materially inflated prices throughout the Class Period.

46. As information concerning the true nature and extent of Amarin's practices gradually became known, however, the value of Amarin securities plummeted, causing Lead Plaintiff and the Class to suffer enormous losses.

47. On October 11, 2013, the FDA released its briefing document for the Endocrinologic and Metabolic Drugs Advisory Committee ("AdCom") meeting scheduled for October 16, 2013 ("Briefing Document").

48. The Briefing Document revealed the truth – that Amarin had been informed by the FDA in July 2008 that the FDA's willingness to approve Vascepa for use by a 36 million patient population based only on a 12-week trial, would be influenced by the ACCORD and AIM-HIGH test results, and further that those test results had been unsuccessful.

49. The Briefing Document called into question whether Vascepa offered any meaningful clinical benefit to patients with high triglyceride levels.

50. Upon the release of the Briefing Document, Amarin's shares declined by $1.28 per share – from $6.37 to $5.09 – over 20% -- on volume of over 37.9 million shares.

51. On October 16, 2013, the AdCom voted 9 to 2 against approval of Vascepa for

the ANCHOR indication citing, among other things, concerns regarding the failure of recent cardiovascular outcomes trials (including ACCORD-Lipid and AIM-HIGH) to demonstrate meaningful cardiovascular benefit from reduction in triglyceride levels.

52. On this news, Amarin shares declined an additional $3.16 per share – over 61% on volume of over 105.6 million shares.

53. Meanwhile, the Individual Defendants, and other senior Amarin executives, with knowledge of the undisclosed facts, exercised stock options and sold Amarin ADSs to unsuspecting investors on the open market, garnering unlawful profits in excess of $15 million.

III. JURISDICTION AND VENUE

54. This action arises under Sections 10(b) (15 U.S.C. § 78j(b)) and 20(a) (15 U.S.C. § 78t(a)) of the Securities Exchange Act of 1934, 15 U.S.C. § 78a et seq. (the "Exchange Act"), and Rule 10b-5 (17 C.F.R. § 240.10b-5) promulgated thereunder by the SEC, and is brought on behalf of investors who purchased Amarin ADSs on the open market, or pursuant to Registration Statements filed with the SEC during the Class Period.

55. In connection with the acts alleged herein, the Defendants directly or indirectly used the means and instrumentalities of interstate commerce, including the United States mails and facilities of a national exchange.

56. Jurisdiction is conferred upon this Court by Section 27 of the Exchange Act (15 U.S.C. § 78aa) and 28 U.S.C. §§ 1331 and 1337. This action arises out of the laws of the United States. The Courts of the United States have exclusive jurisdiction of claims brought under the Exchange Act under 15 U.S.C. § 78aa.

57. This Court has personal jurisdiction over the Defendants pursuant to Section 27 of the Exchange Act (15 U.S.C. § 78aa) because Defendants have sufficient contacts with the

United States through their regular and substantial transaction of business therein and exercising jurisdiction over those Defendants is reasonable.

58. Venue is proper in this District because Amarin maintained offices in this District during the Class Period and many of the acts and transactions constituting the violations of law herein complained of occurred within this District, including the preparation and dissemination of materially false and misleading financial statements and corporate documents.

IV. PARTIES

59. Court-appointed Lead Plaintiff James Reiss is a citizen of the State of Illinois. As set forth in his previously submitted Declaration and Certification filed with his motion to be appointed Lead Plaintiff, Reiss purchased over 3.9 million ADSs of Amarin during the Class Period and suffered damages in excess of $8 million as a result of the violations of the federal securities laws alleged herein.[1]

60. Defendant Amarin is a British corporation, headquartered in Dublin, Ireland, with U.S. offices at 1430 Route 206, Suite 200, Bedminster, New Jersey 07921, conducting business within New Jersey and this judicial district. Amarin ADSs trade on the NASDAQ Stock Exchange Global Market ("NASDAQ") under the symbol AMRN.

61. According to its Annual Report filed on Form 10-K for the year ended December 31, 2013, "[t]he aggregate market value of the voting and non-voting common equity held by non-affiliates of [Amarin] as of June 30, 2013 was approximately $785 million, based upon the closing price on the NASDAQ Capital Market reported for such date. 172,440,210 shares held as American Depository Shares (ADS), each representing one Ordinary Share, 50 pence par value per share, and 465,853 Ordinary Shares, were outstanding as of February 20, 2014."

[1] Lead Plaintiff's trades (listed by settlement date) are set forth in Exhibit A to his Declaration and Certification in support of his Motion for Consolidation, Appointment as Lead Plaintiff and Approval of Selection of Lead Counsel and Liaison Counsel, dated January 3, 2014 (Dkt. Nos. 18-6 and 18-7).

62. Amarin is a biopharmaceutical company focused on the commercialization and development of therapeutics to improve cardiovascular health. Vascepa® (icosapent ethyl) is Amarin's first FDA approved product.

63. Defendant Joseph S. Zakrzewski ("Zakrzewski") was the Chairman and Chief Executive Officer of Amarin, having joined Amarin in January 2010. Zakrzewski was a direct, substantial and primary participant in the securities fraud alleged herein. He was appointed CEO effective November 10, 2010 and subsequently retired as Chief Executive Officer and Chairman of the Board of Directors of Amarin, effective January 1, 2014. Zakrzewski has remained a member of Amarin's Board of Directors. As Amarin's CEO, Zakrzewski was Amarin's primary spokesperson on investor conference calls, investor presentations, and in press releases, had actual knowledge of, and/or supervision over, Amarin's communications with the FDA and the undisclosed facts concerning the FDA approval process.

64. Defendant John F. Thero ("Thero") served as Amarin's President and Principal Financial Officer from November 2009 to January 1, 2014, when he replaced Zakrzewski as CEO and was appointed to the Amarin Board of Directors. As Amarin's President and Principal Financial Officer, Thero was a frequent spokesperson on investor conference calls, investor presentations, and in press releases, and had actual knowledge of, and/or supervision over, Amarin's communications with the FDA and the undisclosed facts concerning the FDA approval process. He was a direct, substantial and primary participant in the securities fraud alleged herein.

65. Defendant Steven B. Ketchum ("Ketchum") has served as Amarin's Senior Vice President and President of Research and Development since February 2012. Ketchum was a direct, substantial and primary participant in the securities fraud alleged herein. As Amarin's

Senior Vice President and President of Research and Development, Ketchum was Amarin's primary liaison with the FDA as well as an Amarin spokesperson on investor conference calls, and had actual knowledge of, and/or supervision over, Amarin's communications with the FDA and the undisclosed facts concerning the FDA approval process.

66. Defendants Zakrzewski, Thero, and Ketchum are referred to herein collectively as "Individual Defendants." Amarin, as a corporation, is charged with the actual knowledge of each of its senior officers, including each of the Individual Defendants. Each of the Individual Defendants' statements alleged herein was made within the scope of his authority and is therefore chargeable against the Company.

V. CLASS ACTION ALLEGATIONS

67. Lead Plaintiff brings this action as a class action pursuant to Rules 23(a) and 23(b)(3) of the Fed. R. Civ. P. on behalf himself and all other persons or entities who purchased Amarin ADSs on the open market, or pursuant to Registration Statements filed with the SEC during the Class Period. Excluded from the Class are Defendants, present or former executive officers of Amarin, and the Individual Defendants' immediate family members (as defined in 17 C.F.R. § 229.404, Instructions (1)(a)(iii) and (1)(b)(ii)).

68. The members of the Class are so numerous that joinder of all members is impracticable. While the exact number of Class members is unknown to Lead Plaintiff at this time and can only be ascertained through appropriate discovery, Lead Plaintiff believes there are hundreds of members of the Class. Amarin ADSs were actively traded on the NASDAQ Exchange throughout the Class Period.

69. Lead Plaintiff will fairly and adequately protect the interests of the members of the Class. Lead Plaintiff has retained competent counsel experienced in class action litigation

under the federal securities laws to further ensure such protection; he is a member of the Class; his claims are typical of the claims of all Class members; and he does not have interests antagonistic to, or in conflict with, those of the Class.

70. A class action is superior to other available methods for the fair and efficient adjudication of this controversy since a multiplicity of actions could result in an unwarranted burden on the Court system and could create the possibility of inconsistent judgments. Moreover, a class action will allow redress for many persons whose claims would otherwise be too small to litigate individually. There will be no difficulty in the management of this action as a class action.

71. There are numerous questions of law and fact which are common to the Class and which predominate over any questions affecting individual members of the Class, including:

(a) Whether the federal securities laws were violated by Defendants' acts as alleged herein;

(b) Whether the Defendants misrepresented or omitted material facts concerning FDA approval of Vascepa for the ANCHOR indication;

(c) Whether Defendants' statements omitted material facts necessary to make the statements made not misleading in light of the circumstances under which they were made;

(d) Whether Defendants knew or recklessly disregarded that their statements were false and misleading;

(e) Whether Defendants engaged in perpetrating a manipulative and deceptive scheme and/or otherwise engaged in a fraudulent course of conduct;

(f) Whether the prices of Amarin's ADSs were artificially inflated; and

(g) Whether members of the Class were damaged by virtue of their investments in Amarin ADSs during the Class Period, and if so, the appropriate measure of damages.

VI. ALLEGATIONS OF FACT

A. BACKGROUND

1. Amarin and Vascepa

1. Amarin describes itself in SEC filings as a "biopharmaceutical company focused on the commercialization and development of therapeutics to improve cardiovascular health."

2. Vascepa is Amarin's primary product offering and according to Amarin's SEC filings "is an ultra-pure, EPA-only omega-3 fatty acid product" for the treatment of patients with very high and high triglycerides (≥ 500mg/dL) and (≥ 200 mg/dL and >500 mg/dL).

3. According to the American Heart Association's website (most recently updated April 21, 2014), triglyceride is the most common type of fat in the body.

4. In October 2009, Amarin announced that it had ceased development of all product candidates outside of its cardiovascular disease focus. Thus, during the Class Period, Amarin was totally dependent on the future success of Vascepa.

2. FDA New Drug Approval

5. In the United States, pharmaceutical development and marketing is regulated by the FDA, an agency of the U.S. Department of Health and Human Services. The modern regulatory regime was enacted in 1962, after Thalidomide, a sleeping pill, caused birth defects in thousands of babies. In reaction to this tragedy, Congress passed the Kefauver-Harris Amendments to the Food, Drug and Cosmetic Act (the "FDCA") requiring that any company that wanted to market a pharmaceutical product in the United States (known as a "sponsor") had to obtain prior approval from the FDA, and that the approval had to be based upon substantial scientific evidence demonstrating that the product was safe and effective for its intended use in humans.

6. The FDCA, as amended, requires the Commissioner of the FDA to refuse any

drug application if:

(a) there is insufficient information to determine whether such drug is safe for use under such conditions; or

(b) there is a lack of substantial scientific evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof.

7. The FDA is only permitted to consider clinical evidence to be "substantial," and thus satisfy the FDCA, if it:

> consist[s] of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof. [21 U.S.C. § 355 (d)].

8. Well-controlled clinical investigations measure the subject drug against a control group, which is provided either a placebo or another recognized drug for comparison. Moreover, well-controlled clinical investigations are almost always conducted in a "doubleblinded" manner, meaning that the tests are designed so that the study participants and the investigators (as well as the sponsor and associated research organizations) do not know whether each participant has been provided the candidate drug or is a member of the control group. Double-blinding is intended to minimize test bias and error that can arise when the participant or investigator have knowledge of the assigned treatment.

9. When a sponsor believes it has conducted sufficient well-controlled clinical trials, and believes that those trials demonstrate substantial evidence of efficacy and safety consistent with the FDA, the sponsor may prepare and file an New Drug Application ("NDA")

with the FDA seeking approval to market the subject drug in a specific dose for the treatment of a specific condition or "indication." The FDA can only grant approval when presented with scientific evidence meeting the requisite statutory criteria.

10. An NDA accepted for filing is reviewed for substance by the FDA's Center for Drug Evaluation & Research ("CDER"). CDER may (or may not) convene an advisory committee to provide it with technical advice, enhance its decision-making process, and provide a forum for public discussion of controversial issues.

11. Where an advisory committee is convened, the sponsor and the FDA staff will each provide the advisory committee briefing documents and make presentations to the advisory committee. After receiving the submissions of both the sponsor and the FDA, and hearing their respective presentations, the advisory committee will discuss the safety and efficacy of the drug candidate and provide the FDA with a nonbinding vote on specific questions regarding safety and efficacy, and whether approval is warranted based upon the evidence of safety and efficacy provided by the sponsor.

12. An advisory committee is the only forum in which the public can legally be advised by the FDA of the FDA's position and the FDA's interactions with the sponsor regarding the drug candidate. Except in advisory committee briefing documents and during the advisory committee hearing, FDA secrecy regulations strictly prohibit the agency from disclosing information regarding pending NDAs. As a result, without an advisory committee, the FDA may not publicly refute a sponsor's misrepresentations regarding clinical trials, protocols, or the sponsor's interactions with the FDA. See 21 C.F.R. § 314.430.

13. Companies are allowed to make changes to drugs or their labels after they have been approved. To change a label, market a new dosage, indication or strength of a drug, or

change the way it manufactures a drug, a company must submit a supplemental new drug application ("sNDA").

3. MARINE and ANCHOR

14. In 2008, Amarin reported that it was conducting two Phase III registration trials, referred to as the MARINE and ANCHOR studies, for which Amarin began patient enrollment in December 2009.

15. The trials were separate registration trials seeking to demonstrate safety and efficacy for different indications of Vascepa.

16. In the MARINE trial, Vascepa was being studied for the treatment of patients with very high triglycerides with or without co-administration of a statin. Patients with TG levels above 500 mg/dL are at risk of pancreatitis.

17. In the ANCHOR trial, Vascepa was being studied for the treatment of elevated triglycerides in patients with mixed dyslipidemia (≥200 mg/dL and >500 mg/dL) when co-administered with a statin on optimal therapy.

18. Amarin estimated in its public statements that whereas approximately four million patients could benefit from the MARINE indication, the market for the ANCHOR indication was approximately 36 million patients.

19. Both of these Phase III clinical trials were conducted under Special Protocol Assessment (SPA) agreements with the U.S. Food and Drug Administration (FDA).

20. Prior to the approval of Vascepa for the treatment of severe hypertriglyceridemia, the FDA had approved LOVAZA (a competitive drug) for the same indication.

21. Unlike ANCHOR, the MARINE indication was intended to treat a much smaller

and sicker patient population and to treat a different disease (pancreatitis rather than heart disease).

4. Mineral Oil as Placebo

22. Generally, a placebo is seen as an inert substance (unable to elicit an effect), but if the choice of substance is not, in fact, inert, there may be an adverse impact on the reliability of the trial results.

23. A placebo is required to have a similar viscosity and taste as the treatment drug to enable the study to be double-blinded.

24. The ANCHOR trial utilized mineral oil as a placebo.

25. Prior to running the ANCHOR trial, patients in the treatment and control arm were maintained on a statin baseline to ensure stable lipid readings.

26. The ANCHOR study demonstrated adverse lipid test results on placebo compared to baseline statin therapy – including an increase in LDL-C of 8.8% and TGs of 5.9% -- raising the possibility that mineral oil was not inert and had an adverse impact on absorption of the statin.

27. Moreover, the treatment arm (Vascepa plus statin) resulted in a 1.5% increase in LDL-C over baseline. Therefore, in absolute terms, Vascepa did not decrease the reading of LDL-C in the ANCHOR study, but rather only decreased the reading relative to placebo.

28. In September 2011, Confidential Witness A, a senior director of clinical research and medical affairs at Amarin who reported to Paresh Soni, Senior Vice President, Head of Development, was concerned that the mineral oil placebo was not inert and had an adverse impact on the absorption of the statin, resulting in the increase in LDL-C and TG readings in the control arm. Soni informed Confidential Witness A that he too was concerned that mineral oil

was not inert and had discussed his concerns with defendant Zakrzewski.

29. Because of his concern with mineral oil as the placebo, Confidential Witness A recommended to Paresh Soni and Rene Braeckman (Head of Development Operations) that Amarin conduct a small study to compare mineral oil placebo to corn oil and olive oil to determine if there were effects on results. Other similar studies of drugs with similar viscosity and taste to Vascepa at the time were using olive oil or corn oil placebos. Soni and Braeckman rejected any potential study or modifications to the REDUCE-IT protocol because the SPA had been approved by the FDA and the ANCHOR study had been conducted with mineral oil as the placebo. Zakrzewski told Confidential Witness A that he would not allow any change to REDUCE-IT and that this study would meet a budget number and not to answer a scientific question and that Amarin "was not moving backwards." Zakrzewski told Confidential Witness A that he was not changing any studies that would affect the time line of when Amarin could file the sNDA with the FDA for the ANCHOR indication.

30. At the time of these discussions between Confidential Witness A and Zakrzewski, according to Confidential Witness A, there were only 26 employees at Amarin. Confidential Witness A's concerns that mineral oil was not inert and had skewed the test results was discussed again in late 2012, as Amarin was preparing to file the ANCHOR sNDA with the FDA, among the senior Amarin officers most involved with the ANCHOR test study, including Confidential Witness A, Zakrzewski, Soni and Braeckman. Zakrzewski stated in response to those concerns that he had given a timeline to his Board and the public on when the sNDA for ANCHOR would be filed with the FDA and that he was not going to deviate from that timeline to do more studies.

31. According to Confidential Witness A, Soni and Defendant Zakrzewski

constantly argued. Soni would express concern to Zakrzewski in Confidential Witness A's presence that Amarin would not get approval for the ANCHOR indication without completing the REDUCE-IT study and that more investment would have to be made in REDUCE-IT and Zakrzewski would not want to hear it. Zakrzewski brought someone in who was a "yes" man to replace Soni even prior to Soni's departure prior to the AdCom Hearing.

32. Lead Plaintiff has confirmed Confidential Witness A's position at Amarin on LinkedIn.

33. As stated subsequently by the FDA in its October 11, 2013 Briefing Document to the Advisory Committee and at the Advisory Committee meeting itself, the FDA shared Confidential Witness A's concern that mineral oil was not inert and stated that it had met with Amarin to discuss the issue in advance of the Advisory Committee hearing – thus confirming Lead Plaintiff's allegations that Defendants' had actual knowledge of the risk that mineral oil was not inert and misrepresented the true facts to investors. *See* ¶ 409 ("we discussed our concerns with the sponsor"). These discussions likely took place between April 18, 2011 and August 5, 2011, subsequent to the release of the ANCHOR study and prior to the August 5, 2011 REDUCE-IT SPA.

34. The FDA had informed Amarin at the July 2008 meeting that test results would have to be "robust" to justify consideration for approval based on one study of surrogate endpoints. At 8. Because of the added uncertainty caused by the use of mineral oil, and the adverse test results experienced by patients while on placebo, the test results were anything but "robust."

35. Defendants knew that the ANCHOR test results indicated that mineral oil may not be biologically inert, refused to conduct further tests, and misrepresented the truth with

respect to the ANCHOR results to investors.

36. Questions raised by the FDA with respect to the placebo, on issues known to Defendants as early as 2011 (if not earlier), made it substantially less likely that the FDA would approve Vascepa for the ANCHOR indication based only on the ANCHOR study.

5. Statins

37. Patients who require therapy to manage their triglycerides most often are on statin therapy, which is widely used for controlling LDL (bad) cholesterol.

38. Statin drugs are approved by the FDA as an adjunct to diet and exercise to reduce blood levels of LDL (bad) cholesterol.

39. According to the Mayo Clinic, statins work by blocking a substance the human body needs to make cholesterol. Statins may also help the body reabsorb cholesterol that has built up in plaques on artery walls, preventing further blockage in blood vessels and heart attacks.[2]

40. Statins include well-known medications such as atorvastatin (Lipitor), simvastatin (Zocor), lovastatin (Mevacor), pravastatin (Pravachol), rosuvastatin (Crestor) and others. Lower cost generic versions of many statin medications are available.

41. Statins are limited and do not primarily treat TGs. Although LOVAZA has been approved only for patients with very high hypertriglyceridemia, it has been used off-label by physicians in the larger population of patients with high TGs. Amarin promoted the potential market for Vascepa with patients currently receiving statin treatment to reduce LDL (bad) cholesterol levels as compared to GlaxoSmithKline's LOVAZA. Amarin has contended that unlike Vascepa, LOVAZA works against statins and although LOVAZA causes a reduction in

[22] http://www.mayoclinic.org/diseases-conditions/high-blood-cholesterol/in-depth/statins/art-20045772

TGs it also causes an increase in LDL (bad) cholesterol.

6. Amarin's July 2008 Meeting with the FDA

42. On July 14, 2008, senior officers of Amarin met with the FDA for the purpose of discussing the 12-week MARINE and ANCHOR studies for testing of Vascepa. As stated in the minutes of that meeting:

The firm requested a meeting to discuss a potential development plan for the following indications:

> 1. As an adjunct to diet to reduce triglyceride (TG) levels in adult patients with very high (>500 mg/dL) TG levels [the MARINE indication].[3]
>
> 2. As an adjunct to diet to reduce TG levels in adult patients with high (>200 mg/dL) TG levels not controlled by diet and HMG CoReductase (statin) therapy [the ANCHOR indication].

43. Amarin, at that meeting, asked whether the design of ANCHOR was "adequate to provide the clinical efficacy data necessary to support the proposed indication?"

44. According to the FDA's Minutes of that meeting, the FDA informed Amarin at that meeting that there were no existing long-term studies that established that the introduction of a second drug for the treatment of TGs (such as Vascepa) as an adjunct to a statin significantly reduced residual cardiovascular risk ("we are not aware of any prospective, controlled clinical trial data demonstrating that pharmaceutical reduction of non-HDL-C (or TG) with a second drug in patients with elevated TG Levels at LDL goal on statin therapy, significantly reduces the residual risk for CVD").

45. The FDA further informed Amarin that three then ongoing studies (AIM-HIGH, ACCORD and IMPROVE-IT) "will provide important information on the incremental benefit of adding a second lipid-active drug to statin therapy." The FDA thus informed Amarin (given

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[3] The Court, in its June 29, 2015 Opinion, referenced the first "MARINE" indication as the "ANCHOR indication," and the second "ANCHOR" indication as "an unnamed and more specific indication than the ANCHOR indication, which Amarin apparently abandoned." *See* Opinion at 17, n.13.

the lack of existing scientific evidence supporting surrogate endpoints), that the prospect for approval of Vascapa for the ANCHOR indication, based only on the ANCHOR study, would be influenced by the results of the ACCORD-Lipid and AIM-HIGH studies.

46. At the Advisory Committee meeting on October 16, 2013¸ Mary Roberts, a Clinical Reviewer with the FDA, testified (at 132) that Amarin was informed specifically at the July 2008 meeting, as reflected in formal minutes of that meeting, that FDA approval of Vascepa for the ANCHOR indication would be influenced by the success of the ACCORD-Lipid and AIM-HIGH trials:

> Discussions between the division and the sponsor regarding the development of Vascepa for dyslipidemia began in 2008….
>
> In regards to the population with persistently high triglycerides on statin therapy, the minutes from this meeting reflect the division's uncertainty, which was conveyed to the sponsor regarding whether pharmacological reduction of non-HDL or triglycerides would translate into additional cardiovascular benefit among patients already treated with statins.
>
> Specifically, the sponsor was told the AIM-HIGH, ACCORD, and PROVE-IT studies will provide important information on the incremental benefit of adding a second lipid active drug to statin therapy. Furthermore, the division stated, "Before accepting an application for a treatment indication in this population, at a minimum, a cardiovascular outcomes trial needs to be well underway at the time of review of the 12-week lipid endpoint study." [Emphasis added.]

47. In other words, the FDA had alerted the Company that having the REDUCE-IT study "substantially underway" would not be sufficient for approval depending on the outcomes of the ACCORD and AIM-HIGH trials.

48. According to FDA guidance, "[d]ocumentation of meeting outcomes, agreements, disagreements, and action items is critical to ensuring that this information is preserved for meeting attendees and future reference. FDA minutes are the official record of the meeting. The official, finalized minutes will be issued to all FDA attendees (with copies to

appropriate files) and to the sponsor or applicant within 30 days of the meeting."[4] [Emphasis added.]

49. Further, the July 2008 FDA meeting was not just any meeting -- it concerned the sine qua non of Amarin's business.

50. Defendants, in connection with their motion to dismiss the CAC, moved to seal the July 14, 2008 Minutes on grounds that they contained information that was a "trade secret and competitively sensitive." Dkt. No. 55-1, ¶ 4. Defendants argued that "[a] competitor could use this information to shortcut its own development process by ascertaining what information from Amarin the FDA viewed as preliminarily acceptable." *Id.; see also* Dkt. No. 55-2, at 4 ("The 2008 Minutes contain confidential business information as well as trade secret information, disclosure of which would injure Amarin's standing in the marketplace by revealing key, confidential, and proprietary information about the composition and testing of Vascepa.").

51. Information that is so "key, confidential and proprietary" that it is required to be filed under seal five years later is certainly information that is sufficiently "key" to have been known to the Individual Defendants, and its other senior officers such as Declan Doogan and Paresh Soni, or which should have been known if not for their reckless disregard of the truth.

52. Amarin, in a March 2015 filing in the DC Action against the FDA has given great weight to and has sought to bind the FDA to its "preliminary responses" at the July 2008 meeting. *See* Amarin's Supplemental Submission in Response to the Court's Questions, dated March 24, 2015, DC Dkt. No. 28 at 3 ("As memorialized in the meeting minutes issued by FDA on August 13, 2008, FDA indicated that Vascepa was a new chemical entity entitled to five-year exclusivity during Amarin's Pre-IND meeting with FDA on July 14, 2008."). Amarin

[4] http://www.fda.gov/downloads/Drugs/Guidances/ucm153222.pdf

further argued in the DC Action that it relied on those "preliminary responses" in conducting a four-week transgenic mouse toxicity study beginning March 2009. *Id.* at 4.

53. On at least five occasions prior to and during the Class Period defendants made materially false and misleading statements concerning the ACCORD or AIM-HIGH studies:

a. At a Thomson Reuters Future Leaders in the Biotech Industry Conference, on April 8, 2010, Declan Doogan, as Interim Chief Executive Officer, stated, on behalf of Amarin, that whereas the ACCORD study had been a failure and demonstrated the disutility of fibrates in treating cardiovascular disease, JELIS had been a success and demonstrated the utility of ethyl-EPA, the active ingredient in Vascepa, in treating CV disease.

b. In a presentation on May 3, 2010 at the Deutsche Bank Securities Health Care Conference, defendant Thero stated that fibrates had been dealt a setback in treating triglycerides by virtue of the ACCORD study.

c. Declan Doogan, in a presentation to the Rodman & Renshaw Global Investment Conference, on May 19, 2010, as Chief Executive Officer of Amarin, again contrasted the success of the JELIS study to the failure of ACCORD ("which failed to show significant benefit in cardiovascular risk modification").

d. Defendant Zakrzewski, on an April 18, 2011 Amarin conference call, stated that the ACCORD failure provided a competitive benefit for Vascepa ("[I]n the ACCORD studies and others, Trilipix and others didn't perform very well, particularly in high statin does. And so we think that's another real benefit for us.").

e. Defendant Ketchum presented on an August 8, 2013 conference call (¶ 381) that the failure of ACCORD and AIM-High would not have implications on approval of Vascepa.

54. At no time did defendants disclose the truth that the FDA had informed Amarin in July 2008 that the AIM-High and ACCORD trials "will provide important information on the incremental benefit of adding a second lipid-active drug to statin therapy," and therefore that the failure of the AIM-High and ACCORD studies would bear on the willingness of the FDA to approve ANCHOR based only on a twelve-week study of surrogate endpoints.

7. The June 6, 2009 SPA Further Demonstrates the FDA's Substantial "Uncertainties Around the Science Supporting TG as a Surrogate for CV Risk."

55. In early 2009, Amarin submitted to the FDA the Protocol for the ANCHOR trial and requested that the FDA enter into a SPA that if the ANCHOR trial achieved its endpoints that the FDA would approve Vascepa for the high TG indication. The FDA responded and signed the SPA on July 6, 2009.

56. Although the FDA stated "yes" when asked in the July 6, 2009 SPA whether the "design and size" of ANCHOR was adequate to demonstrate a statistically significant reduction in TGs to "support" the proposed indication, the FDA answered that it was a "review issue" when asked if a statistically significant reduction in TG "will provide an adequate basis for *approval* for the indication" (emphasis added):

> Does the FDA agree that if the results of this study show a statistically significant reduction in TG and rule out a 6% LDL-C increase, it will provide an adequate basis for approval for the indication: "as an adjunct to diet to reduce triglyceride (TG) levels in patients with high (>200 mg/dL) TG levels not controlled by diet and statin therapy"?

FDA Response: This is a review issue. [Emphasis in the original.]

57. Thus, the FDA categorically rejected Amarin's contention that the SPA mandated FDA approval of the ANCHOR indication based only on evidence of TG lowering in the ANCHOR study.

58. Amarin, in its November 7, 2013 letter to the FDA (NY Dkt. No. 64-1) acknowledged (at 17-24) that both Amarin and the "FDA ha[d] been aware that lipid lowering surrogate endpoints (other than statin-lowered LDL-C), such as TG, might not be predictive of CVD risk reduction for years prior to the entry into the ANCHOR SPA agreement [July 2009] and the start of the ANCHOR trial."

59. Amarin has further acknowledged in correspondence with the FDA that in the aftermath of the July 14, 2008 meeting and July 6, 2009 SPA that: "Both parties understood that the potential for CV risk reduction in an ANCHOR-like patient population could not be resolved until the ultimate outcome of the ongoing REDUCE-IT trial." Ketchum November 7, 2013 Letter, NY Dkt. No. 64-1, at 47-48. *See also* NY Dkt. No. 64-5 at 5 [Letter dated February 27, 2015 to Curtis J. Rosebraugh] ("the enrollment requirement also reflects the Division's recognized substantial uncertainties around the connection between the potential effects of Vascepa on the studied lipid and lipoprotein parameters in the ANCHOR population and cardiovascular risk reduction").

60. This is exactly the point that the FDA made in the July 14, 2008 minutes that "we are not aware of any prospective, controlled clinical trial data demonstrating that pharmacologic reduction of non-HDL-C (or TG) with a second drug inpatients with elevated TG levels at goal on statin therapy significantly reduces the residual risk for CVD."

61. The July 14, 2008 Minutes and July 6, 2009 SPA left unresolved whether the FDA would require that long-term the REDUCE-IT be completed before FDA approval of ANCHOR would be granted. Dr. Rosebraugh in his April 22, 2014 letter to defendant Ketchum (NY Dkt. No. 53-7 at 31), exposed the duplicity in Amarin's position that (i) it should get ANCHOR approval based on a TG surrogate endpoint, and (ii) Amarin's acknowledgement of the FDA's position as early as 2008 and 2009 that TG was ineffective as a surrogate endpoint for CVT:

> Further regarding your argument that it was well known prior to initiation of the ANCHOR study that drug-induced modulation of lipid endpoints, by non-statin drugs, may not reduce CV risk, it is odd that you are bringing this up now and not at the time of DMEP's assertion in 2008 that ACCORD-Lipid and AIM-HIGH would provide important information. It would seem that if you had questions at that time regarding the use of TG as a surrogate, you would have addressed them. Yet you

> seem to have remained mute on the subject, but now seem to be saying you knew that all along. It is an interesting position that you have adopted, in that you thought TG wasn't predictive when you entered into the SPA agreement, but you would be happy to receive an indication for use based on a non-predictive surrogate. [Emphasis added]

See also Rosebraugh April 22, 2014 letter at 15 ("This all fairly indicates an outcomes trial with objective endpoints should be completed before the Agency can approve a new indication that Vascepa is likely to lower CVD in patients on statin therapy.").

62. Upon or prior to joining Amarin, Defendant Zakrzewski and the other Individual Defendants certainly would have reviewed Amarin's file of communications with the FDA and would have been apprised of the facts of the July 2008 meeting, including the association that the FDA drew between approval of Vascepa for the ANCHOR indication (based only on the ANCHOR 12-week trial) and the success of the ACCORD-Lipid and AIM-HIGH outcomes trials. These materials go to the essence of the Company's business.

63. Curtis J. Rosebraugh, in his April 22, 2014 letter to defendant Ketchum, NY Dkt. No. 53-7, at 6, admonished Ketchum for disregarding the FDA's cautionary warnings at the July 14, 2008 pre-IND meeting with respect to ACCORD and AIM-HIGH, as well as the requirements and limitations of the July 6, 2009 SPA:

> You mention that you were unaware of how tenuous DMEP's confidence was in TG as a surrogate. I found these statements difficult to accept after reviewing the regulatory history. The fact that DMEP felt a CVOT was necessary, and that you agreed to conduct one, indicates the fragile nature of the evidence supporting TG's hold onto surrogate status. Also, as early as the pre-IND meeting of July 14, 2008, you were informed that there was no evidence that pharmacological reduction of non-HDL-C (or TG) with a second drug in patients with elevated TG levels at LDL-C goal on statin therapy significantly reduces the residual risk for CVD. Further DMEP stated that the ACCORD-Lipid and AIM-HIGH studies, while not designed to address this specific gap in knowledge, would provide important information on the incremental benefit of adding a second lipid-active drug to statin therapy. [Footnote omitted.]

64. Dr. Rosebraugh concluded in his April 22, 2014 letter (again at 16) that "I cannot

give credibility to your assertions that these facts were minor and did not warrant importance or continued consideration on your part."

65. Dr. Rosebraugh was a sophisticated practitioner with personal knowledge of the facts, who recognized Amarin's duplicity in claiming to have been unaware of the FDA's warnings. At the time of his April 22, 2014 letter, Dr. Rosebraugh was the Director and most senior member of the FDA's Office of Drug Evaluation II, having been appointed to that position in June 2008. According to the FDA's website, Dr. Rosebraugh is "responsible for protecting the public health by assuring safe and effective drugs and biologics are available to the U.S. population."

66. Dr. John Jenkins, Director, Office of New Drugs, Center for Drug Evaluation and Research, in his letter to Dr. Ketchum dated September 11, 2014 NY Dkt. No. 53-11 at 3, also criticized Ketchum and others at Amarin for not recognizing the obvious implications of the FDA's statements in the July 6, 2009 ANCHOR SPA. Dr. Jenkins (at 3) accused Amarin of requiring the FDA to have "speculat[ed] on potential results of the ANCHOR trial and the adequacy of those results to inform a benefit risk assessment to support approval":

> In response to two other questions posed by Amarin with regard to hypothetical ANCHOR study results and their adequacy to support approval and/or labeling statements for Vascepa for the proposed indication, DMEP stated, "This is a review issue." DMEP acted correctly in limiting its agreement under the ANCHOR SPA to issues related to "the design and size [] of clinical trials intended to form the primary basis of an effectiveness claim" in a marketing application and not speculating on potential results of the ANCHOR trial and the adequacy of those results to inform a benefit risk assessment to support approval. Although at the time of the pre-IND meeting on July 18, 2008, (as well as at the time of the ANCHOR SPA agreement) DMEP was still willing to accept TG lowering as a validated surrogate for reducing CV risk, DMEP made clear to Amarin that there were still concerns regarding whether reducing TG in the patient population proposed for the ANCHOR trial would reduce CV risk; i.e., whether reducing TG levels in patients on statin therapy could be relied on as a validated surrogate for reducing CV risk. DMEP also made clear that it was aware of ongoing cardiovascular outcome trials (CVOTs) that would provide important information to better inform this issue [referencing and quoting

the July 14, 2008 Meeting Minutes]. [Footnotes omitted; emphasis added.]

67. Similarly, at page 10, fn. 33 of his September 11, 2014 letter, Dr. Jenkins states:

> In your FDRR you state that in the July 6, 2009, ANCHOR SPA agreement letter that DMEP agreed to a proposed indication "as an adjunct to diet to reduce triglyceride (TG) levels in patients with high (>200 mg/dL) TG levels not controlled by diet or statin therapy." In fact DMEP stated in response to Amarin's question on whether the division agreed to that proposed indication, that "This is a review issue."

68. Dr. Jenkins further accused Amarin (at 7-8) of bad faith by ignoring the FDA's cautionary warnings with regard to AIM-HIGH and ACCORD:

> It defies logic to now claim that the cumulative results of CVOTs that were ongoing at the time DMEP entered into the SPA agreement cannot be viewed as new scientific information relevant to a determination of whether decreases in TG can be considered a validated surrogate…. DMEP made Amarin aware of its concerns and was under no obligation to include a "condition" in the SPA agreement that linked the agreement to the results of ongoing CVOTs.

69. Dr. Jenkins was at the time of his September 11, 2014 letter, the Director of the Office of New Drugs at the FDA's Center for Drug Evaluation and Research.

70. On October 29, 2013, as alleged herein, the FDA rescinded the July 6, 2009 SPA, citing results from the ACCORD, AIM-HIGH- and HPS2-THRIVE CVOT studies as establishing that "a substantial scientific issue essential to determining the effectiveness of Vascepa in this [high TG] population was identified after testing began." *See* NY Dkt. No. 53-10.

71. In its efforts to have the FDA reinstate the SPA, defendants have argued that the CVOTs did not provide new information after ANCHOR testing had begun, but only information that was anticipated by Amarin and the FDA as of 2008 and 2009. Thus, Amarin acknowledged recognizing by 2009 that the requirement in the SPA that Amarin complete 50% enrollment in the REDUCE-IT CVOT reflected the FDA's "uncertainty around the science supporting TG as a surrogate for CV risk":

> As part of the ANCHOR SPA agreement, due to the Division's uncertainty around TG as a surrogate for CV risk, the Division required and Amarin agreed to complete 50% enrollment in a Vascepa cardiovascular outcomes trial (CVOT), called the REDUCE-IT trial, before the Division would accept submission of a supplemental new drug application (sNDA) for approval of an indication based on the ANCHOR study. This represented a substantially higher bar for approval of a TG-lowering indication than FDA had applied to other applications for this indication, indicative of the Division's uncertainty around the science supporting TG as a surrogate for CV risk. [Footnote omitted]

See Letter from defendant Ketchum to Dr. Jenkins (Director, Office of New Drugs, CDER, FDA) dated May 22, 2014 NY Dkt. No. 64-4 at 3-4. *See also* Ketchum February 27, 2014 letter, NY Dkt. No. 64-5 at 5 (referencing the FDA's "substantial uncertainties").

72. In that same May 22, 2014 letter at 5 defendant Ketchum acknowledged that "uncertainty about the validity of TG levels as a surrogate for CV outcomes – existed when the Division agreed to the SPA, and the Division acknowledged it in discussions with Amarin before execution of the SPA agreement."

8. The FDA Has Confirmed in Writing that "Approximately Five Pages" of Written Communications Between the FDA and Amarin Relate to the Interrelationship Between Prospective Approval of the ANCHOR Indication and the ACCORD-Lipid and AIM-HIGH Trials

73. By letter dated October 31, 2013, Lead Counsel requested, pursuant to the Freedom of Information Act, that the FDA provide documents including but not limited to "the Special Protocol Assessment Agreement (SPA) entered into between the FDA and Amarin in or about 2009 for its planned Phase III ANCHOR clinical trial of Vascepa (ethyl-EPA) in patients with mixed dyslipidemia, as well as any documents concerning communications between the FDA and Amarin concerning revisions, iterations, or rescissions of the SPA."

74. Lead Counsel specifically requested "documents concerning communications with Amarin, regarding whether Amarin would be required, prior to FDA approval of Vascepa

for the ANCHOR indication, to complete the REDUCE-IT clinical trial and any documents concerning communications with Amarin related to the REDUCE-IT study, the ACCORD-Lipid study, the AIM-HIGH and the HPS2-THRIVE study."

75. In a letter dated November 14, 2013 the FDA confirmed that there are "approximately five pages" of documents responsive to plaintiffs' request (although the FDA did not indicate whether those are five separate pages in five documents or five pages in one document, or something in between). The FDA however denied Lead Counsel's request to provide the five pages of documents based, among other things, on the FOIA exemption for trade secrets. 5 U.S.C. 552 (b)(4).

76. Pursuant to 45 CFR § 5.34, on December 12, 2013, Lead Counsel submitted an appeal from the FDA's November 14, 2013 denial. The FDA subsequently denied the FOIA appeal, but plaintiffs are continuing to seek disclosure of the FDA's Vascepa regulatory file through the FOIA regulatory process in light of the June 2015 disclosure of much of the FDA regulatory record in the NY Action. Among the documents that plaintiffs are seeking disclosure of are minutes of meetings between the FDA and Amarin conducted on March 16, 2011 and April 13, 2011.

9. The ACCORD-Lipid Study

77. Abbott Laboratories ("Abbott") had submitted an NDA to the FDA for fenofibric acid (tradename Trilipix) in 2007. Abbott sought approval of Trilipix for three indications, including the treatment of patients with mixed/artherogenic dyslipidemia, primary hypercholesterolemia or mixed dyslipidemia, and primary hypertriglyceridemia.

78. The assessments of the clinical efficacy and safety of Trilipix were based in large part on data from three randomized, double-blind, active-controlled trials of 12-weeks duration

followed by an open-label extension (similar to ANCHOR). Approximately 2700 patients with mixed dyslipidemia were enrolled into the three studies combined.

79. The studies tested Trilipix both as monoline therapy in comparison to statins and as add-on therapy in combination with a statin. Those 12-week studies were successful in demonstrating statistically significant improvements in HDL-C, LDL-C and TG levels (surrogate endpoints) in the treatment arms of certain of the patient populations.

80. The test results reported by Abbott for Trilipix based on 12-week trials, were considered surrogate endpoints, because they established improvements in endpoints that are considered associated with major adverse cardiac events (HDL-C, LDL-C and TG levels), but did not test for improvements in major adverse cardiac events themselves.

81. The ACCORD clinical trial investigated the concomitant use of fenofibrate and a statin against statin monotherapy in a population with moderately elevated TG. ACCORD was initiated by the National Heart, Lung and Blood Institute (NHLBI) in 2001 to answer the following question: In middle-aged or older people with type 2 diabetes who are at high risk for having a cardiovascular disease (CVD) event, does a therapeutic strategy that uses a fibrate to raise HDL-C/lower TG levels and uses a statin for treatment of LDL-C reduce the rate of CVD events compared to a strategy that only uses a statin for treatment of LDL-C.

82. ACCORD was one of the largest studies ever conducted in adults with type 2 diabetes who were at especially high risk of cardiovascular events, such as heart attacks, stroke, or death from cardiovascular disease. The lipids targeted for intensive treatment were HDL cholesterol and triglycerides, in addition to standard therapy of lowering LDL-C.[5]

83. In the ACCORD study, the statin drug simvastatin (Zocor™) was given to all

[5] http://www.nih.gov/news/health/mar2010/nhlbi-15.htm

participants as necessary to control their level of LDL cholesterol according to current treatment guidelines. Participants were randomly assigned to receive either the fibrate drug fenofibrate (Tricor™) or a matching placebo (pill with no active drug).

84. The primary outcome was major cardiovascular events. Over 10,000 subjects with type 2 diabetes took part in the study and the mean follow-up was almost five years.

85. The ACCORD-Lipid trial was ongoing at the time of Amarin's July 2008 meeting with the FDA.

10. The AIM-HIGH Trial

86. The AIM-HIGH trial was funded by the National Heart, Lung, and Blood Institute and began in September 2005. The AIM-HIGH trial studied whether HDL (good) cholesterol levels in patients who have a history of cardiovascular disease and well-controlled LDL (bad) cholesterol levels could lower the rate of major adverse cardiovascular events (MACE).

87. In AIM-HIGH, MACE was defined as cardiovascular death, non-fatal heart attack, ischemic stroke, hospitalizations for acute coronary syndrome in which there is insufficient blood flow to the heart, or revascularization procedures to improve blood flow in the arteries of the heart and brain.

88. In this trial, all study participants were given standard therapy with simvastatin 40 mg per day, and then randomly assigned to receive either extended-release niacin 1500-2000 mg per day or placebo. In the first year of the trial, the simvastatin dose could be adjusted, or a second LDL cholesterol-lowering drug, ezetimibe 10 mg, could be added, to achieve the target LDL-cholesterol goal of 40-80 mg/dL.

89. High-dose niacin is a prescription drug that is used along with diet and exercise

to manage cholesterol and triglyceride levels in the blood. It is also indicated as a monotherapy to lower the risk of heart attacks in patients who have had a heart attack and have high cholesterol.

90. Like the ACCORD trial, AIM-HIGH was ongoing at the time Amarin met with the FDA in 2008.

11. HPS2-THRIVE TRIAL

91. In addition to ACCORD and AIM-HIGH, another trial – HPS2-THRIVE (Treatment of HDL to Reduce the Incidence of Vascular Events) – was undertaken to test the impact of cholesterol on serious adverse cardiovascular events. Specifically, HPS2-THRIVE was designed to test the hypothesis that increased levels of HDL (good) cholesterol, would reduce the risk of serious adverse cardiovascular events.

92. The HPS2-THRIVE study began in January 2007 and was also part of the landscape when Amarin met with the FDA in 2008.

93. By virtue of the July 2008 meeting with the FDA, Amarin knew that even if Vascepa was effective in reducing TGs in the ANCHOR study, that it was the FDA's position that "there was a lack of prospective, controlled clinical trial data demonstrating that pharmaceutical reduction" of TG "significantly reduces residual cardiovascular risk," and that if the AIM-HIGH and ACCORD-Lipid and HPS2-THRIVE studies failed to demonstrate effectiveness in reducing major cardiovascular events, the FDA was substantially less likely to approve the ANCHOR indication prior to completion of the REDUCE-IT study.

12. The IMPROVE-IT Study

94. The third study referenced by the FDA at the July 14, 2008 meeting (IMPROVE-IT) was not released until November 17, 2014 approximately one year after the class period.

95. The IMPROVE-IT study results were not known to Defendants prior to November 17, 2014. Commentators however have criticized the study and called the results "modest." *See* "IMPROVE-IT: 'Modest' Benefit When Adding Ezetimibe to Statins in Post-ACS Patients," November 21, 2014: available at www.medscape.com.

13. The JELIS Study

96. The Japan Eicosapentaenoic acid (EPA) Lipid Intervention Study, or JELIS study was the first large-scale, prospective, randomized trial of combined treatment with a statin and an omega-3 fatty acid originally derived from fish, eicosapentaenoic acid (EPA). The study tested the effects of long-term use of EPA in addition to a statin in Japanese patients with hypercholesterolemia.

97. The JELIS investigators concluded that JELIS showed that the addition of EPA to statin therapy provides additional benefit in preventing major coronary events, apparently through lipid-independent mechanisms.

98. Prior to and throughout the Class Period, Defendants cited the JELIS study as support for the efficacy of Vascepa for the ANCHOR indication.

99. In a January 11, 2010 press release, Amarin stated "[n]umerous independent studies [referencing JELIS] have demonstrated the safety, tolerability and efficacy of ethyl-EPA [the active ingredient in Vascepa] in lowering plasma triglycerides in patients with high triglyceride levels of varying degrees of severity."

100. JELIS, however, was not sufficiently comparable to the ANCHOR trial to warrant Defendants' comparisons. Significantly, the ANCHOR trial was double-blind (neither participants nor researchers were aware of which treatment each participant was receiving), whereas JELIS was open-label (both participants and researchers knew which treatment was

being administered).

101. Defendants had actual knowledge of critical distinctions between JELIS and ANCHOR and REDUCE-IT and knew that the JELIS study was not indicative of efficacy of Vascepa for the ANCHOR indication.

102. The FDA, at the July 14, 2008 meeting, explicitly advised Amarin that it rejected Amarin's contention "that JELIS supports an indication for Ethyl-EPA add-on therapy to a statin in patients at LDL goal who require additional lowering of TG or non-HDL." *See* NY Dkt. 56-3 at 9.

103. The FDA told Amarin at that meeting, according to the meeting minutes (*id.*), that "there are a number of problems with applying the results of JELIS to the US population." *See supra* at ¶ 22.

104. The Briefing Document specifically highlighted this distinction, stating "the open-label study designs of GISSI-P and JELIS … may have introduced bias in patient/physician behavior that could have confounded the treatment effect, particularly in physician-directed outcomes such as hospitalization and interventional procedures."

105. Additionally, as acknowledged in the Briefing Document, whereas over 90% of the patients in the ANCHOR trial were on medium to high doses of statins, by design, all of the patients in the JELIS study were on low doses of statin.

106. When Defendants chose to speak about JELIS, they had an obligation to disclose the whole truth, including the FDA's position that JELIS was not indicative of efficacy of Vascepa for the ANCHOR indication.

107. A reasonable investor would have wanted to know the whole truth, including the FDA's position on the matter.

108. The FDA's articulated position that the JELIS study was not supportive of Amarin's ANCHOR sNDA made it substantially less likely that the FDA would approve Vascepa for the ANCHOR indication based only on a two-week trial, than would have been apparent to a reasonable investor based only on the information publicly disclosed by Defendants.

109. Subsequent to the Class Period, Defendants officially corrected their materially false and misleading statements concerning JELIS by highlighting in the fiscal 2013 Form 10-K (filed with the SEC on February 27, 2014, at 35) "several limitations to the JELIS study":

> However, there are several limitations to the JELIS study. First, the patient population was exclusively Japanese, the majority of the participants were women, and at baseline patients had a much higher LDL, limiting its generalizability to the intended target population. Second, a low dose of statins was used. It is unknown whether the positive treatment effects would have persisted if these patients had been optimally treated with statins using contemporary LDL targets in the United States. Third, JELIS was an open-label trial, which could influence patient and physician behavior and reporting of symptoms, decisions regarding hospitalization, and referral of events for adjudication. This may be particularly relevant since hospitalizations for unstable angina was a primary contributor of the overall positive result, and is considered a softer endpoint than fatal cardiovascular events.

VII. PRE-CLASS PERIOD REPRESENTATIONS

110. In the aftermath of its July 2008 meeting with the FDA, Amarin misrepresented in communications with investors its discussions with the FDA. Recognizing the need to raise capital to conduct the REDUCE-IT study, Amarin began a practice of speaking publicly and optimistically about the likelihood of FDA approval of Vascepa for the ANCHOR indication without completing an outcomes study, without disclosing the FDA's advice to the Company of the significance of the ACCORD-Lipid and AIM-HIGH trial results.

111. On at least fifteen occasions prior to and during the Class Period, Defendants misrepresented to investors that a long-term outcomes study (REDUCE-IT) was not required to

obtain FDA approval for the ANCHOR indication, when Defendants knew that such a study was likely to be required depending on the outcome of the ACCORD-Lipid and AIM-HIGH trials. Defendants also misrepresented that TG reduction was an accepted surrogate for adverse cardiac events and that the failures of ACCORD and AIM-HIGH improved Amarin's competitive standing. *See* citations, *infra*., at ¶ 209.

112. Defendants' false statements set the stage for unfounded investor confidence in Amarin leading up to and through secondary offerings in 2011 and 2013.

A. Amarin's September 25, 2008 Conference Call

113. On a September 25, 2008 conference call, approximately 40 days after Amarin's July 14, 2008 meeting with the FDA, Amarin's then Chairman and Chief Executive Officer, mischaracterized Amarin's Vascepa development program as "a near-term, low-risk, high-value development opportunity whose safety has been established and efficacy of EPA-based products proven in multiple studies around the world." [Emphasis added.]

114. Declan Doogan, Amarin's Head of Research and Development, represented on the conference call that:

> As the treatment of dyslipidemia evolves, medical experts now advocate that attention to be focused on triglyceride levels as they are an independent risk factor for cardiovascular disease. Hypertriglyceridemia does not usually occur in isolation and often together with elevated cholesterol. These mixed dyslipidemic states require combination therapy with other products such as statins. [Emphasis added.]

B. The July 9, 2009 Press Release Announcing the SPA With the FDA for the ANCHOR Study

115. On July 9, 2009, Amarin issued a press release entitled "Amarin Received Special Protocol Assessment Agreement from the FDA for Phase III Trial In Mixed Dyslipidemia."

116. The press release announced that Amarin had "reached agreement with the [FDA] under a Special Protocol Assessment (SPA) for its planned Phase III [ANCHOR] clinical trial of [Vascepa] (ethyl-EPA) in patients with mixed dyslipidemia…. The SPA is a written agreement between the Company, as the trial's sponsor, and the FDA regarding the design, endpoints, and planned statistical analysis of the Phase 3 trial."

117. The press release informed investors that "[t]he Company plans to use the results of this Phase III trial as the basis for potentially broadening the label for [Vascepa] beyond treatment for very high triglycerides to include treatment for high trigylcerides…." Emphasis added.

118. The press release also quoted Thomas Lynch, the then Chairman and Chief Executive Officer of Amarin, as saying: "Receiving FDA agreement on this Phase 3 trial in mixed dyslipidemia is an important endorsement of our strategy which aims to provide a more comprehensive label for [Vascepa]." Emphasis added.

119. Defendants' statements prior to the Class Period were materially false and misleading because the "FDA agreement" on the ANCHOR Phase 3 trial was not "an important endorsement of our strategy … to provide a more comprehensive label" for Vascepa. Rather, Amarin, through its senior officers, including Dr. Doogan, had actual knowledge that, at the time of that statement, the requirement that Amarin have a CVOT "substantially underway" coupled with the FDA's comments at the July 14, 2008 meeting, reflected the FDA's "uncertainty around the science supporting TG as a surrogate for CV risk." Amarin's July 6, 2009 press release failed to convey the FDA's concerns with approving Vascepa for the ANCHOR indication based only on a 12-week trial of surrogate endpoints.

120. Other materially false statements prior to the Class Period included a Rodman &

Rensham investor conference conducted on September 11, 2009 quoting Thomas G. Lynch ("[a]nd we're also in discussion with the FDA about – over the long-term this is not required for approval, but a CV outcome study to demonstrate the reduction in cardiovascular risk."); a January 11, 2010 press release quoting Declan Doogan, as Interim Chief Executive Officer (the "Company believes that the result of this [ANCHOR] trial could lead to approval of AMR101 for a significantly larger market opportunity than is currently approved for similar prescription drugs."); a May 13, 2010 press release ("The results of an outcome study are not required for FDA approval of the broader indication."), and an August 10, 2010 second quarter earnings press release ("[T]he results of an Outcomes study are not required for FDA approval of this broader [ANCHOR] indication for [VASCEPA]."). [Emphasis added].

121. Dr. Doogan, as Amarin's interim chief executive officer, was further quoted in the May 13, 2010 press release as stating:

> "We are very pleased with the progress being made in these two pivotal trials. We believe AMR101 has the potential to be a best-in-class prescription omega-3 drug for treating patients with very high triglycerides or high triglycerides with mixed dyslipidemia." Elevated triglycerides are increasingly being recognized as an important independent risk factor for cardiovascular disease. We are encouraged by the progress we are making and by the enthusiasm for these trials from the investigators. We believe this reflects a growing interest in the active management of elevated triglyceride levels and the expectation that AMR101 possesses an appropriate benefit-risk profile." [Emphasis added.]

122. The press release announced that Amarin had "reached agreement with the [FDA] under a Special Protocol Assessment (SPA) for its planned Phase III [ANCHOR] clinical trial of [Vascepa] (ethyl-EPA) in patients with mixed dyslipidemia…. The SPA is a written agreement between the Company, as the trial's sponsor, and the FDA regarding the design, endpoints, and planned statistical analysis of the Phase 3 trial."

123. Doogan was also quoted in an August 10, 2010 press release as stating "Elevated

triglyceride levels are increasingly being recognized and treated as an independent modifiable risk factor for cardiovascular disease in much the same way as elevated LDL cholesterol levels were more than a decade ago."

124. Doogan had actual knowledge that his statements were false in light of his attendance at the July 14, 2008 FDA meeting and the contents of the July 6, 2009 SPA.

125. These statements were false at the time made because the FDA informed Doogan and others at that meeting that "we are not aware of any prospective, controlled trial data demonstrating that pharmacological reduction of non-HDLC (or TG) with a second drug in patients with elevated TG Levels at LDL goal on statin therapy significantly reduces the residual risk of CVD" Accordingly, Doogan and Amarin's other senior officers knew or were reckless in failing to know – because substantial scientific evidence is required for drug approval -- that a long-term outcome study would likely be required prior to ANCHOR approval, especially if the ACCORD and AIM-HIGH outcome studies proved unsuccessful.

126. These statements remained alive and uncorrected and affected the market for Amarin ADS throughout the Class Period.

C. The March 14, 2010 Release of the ACCORD-Lipid Study Results

127. The ACCORD-Lipid study that the FDA identified to Amarin in July 2008 as significant to the FDA's willingness to approve Vascepa without a long-term cardiac outcomes trial proved to be a failure.

128. The ACCORD study results were released on March 14, 2010 and published on April 29, 2010 in The New England Journal of Medicine as, "The ACCORD Study Group Effects of Combination Lipid Therapy in Type 2 Diabetes Mellitus."

129. The study showed the combination of fenofibrate and simvastatin did not reduce

the rate of fatal cardiovascular events, nonfatal myocardial infarction, or nonfatal stroke, as compared with simvastatin alone. A press release by the National Institutes of Health on March 15, 2010, explained in part:

> Overall, the results of the ACCORD lipid trial do not support the use of combination therapy with a fibrate and a statin to reduce cardiovascular disease in most high-risk adults with type 2 diabetes," said lead author Henry N. Ginsberg, M.D., director of the Irving Institute for Clinical and Translational Research at Columbia University College of Physicians and Surgeons, New York City. "Although our analysis suggests that certain patients may benefit from combination therapy, this study provides important information that should spare many people with diabetes unneeded therapy with fibrates.

130. Although the FDA had stated that the ACCORD study "will provide important information," in reckless indifference to the truth, Amarin did not seek out the FDA's response to ACCORD's failure prior to continuing to make public statements concerning ANCHOR.

VIII. MATERIAL MISREPRESENTATIONS AND OMISSIONS

131. The Class Period starts on November 29, 2010, subsequent to the reported failure of the ACCORD study, and when Amarin first released Phase III MARINE data. Although Defendants' public statements were materially false and misleading prior to November 29, 2010, those statements took on greater significance with investors beginning on November 29, 2010, with the release of the positive MARINE surrogate data. Lead Plaintiff reserves the right, based on discovery or otherwise, to begin the Class Period prior to November 29, 2010.

A. Defendants Misrepresent the FDA's Position on Approval of the ANCHOR Indication for VASCEPA and Fail to Disclose the FDA's Misgivings that Reducing Levels of Triglycerides Would Not Reduce Major Cardiovascular Events

132. Throughout the Class Period, beginning November 29, 2010, Amarin misrepresented to investors that, pursuant to the Special Protocol Assessment Agreement agreed to between Amarin and the FDA, the FDA would approve Vascepa based only on the

ANCHOR study, so long as the REDUCE-IT study "was substantially underway."

133. At no time during the Class Period did Amarin disclose that the FDA had expressed reservations about approving Vascepa in the absence of the completion of the long-term REDUCE-IT study. Defendants were required to disclose the FDA's reservations on approval so that Defendants' positive statements on the ANCHOR study were not materially false and misleading – especially since the ACCORD-Lipid study was already disclosed in March 2010 to be unsuccessful in demonstrating a reduction in major cardiovascular events, and the AIM-HIGH study was still underway.

134. Moreover, defendant Ketchum explicitly misrepresented on an August 8, 2013 investor conference call that the failure of the AIM-HIGH and ACCORD studies were irrelevant to the prospects for approval of the ANCHOR indication, even though the FDA had previously advised Amarin that those studies would provide "important information" on the utility of reduced TGs as a surrogate for reduced CV risk.

135. The statements alleged to be false and misleading were not forward looking statements because they misrepresented existing facts based on historical communications with the FDA with respect to the approval process.

136. A reasonable investor during the Class Period would have considered material the FDA's cautionary warning to Amarin in July 2008 that the FDA was substantially less likely to be receptive to the ANCHOR NDA based only on a study of surrogate endpoints since the results of ACCORD-Lipid were already known to be negative. Defendants' transmitting part of the FDA's guidance, by stating that the FDA expressed receptivity to the ANCHOR NDA, but not stating the complete guidance, that the FDA had expressed reservations about ANCHOR approval based only on a surrogate endpoint, was materially misleading to investors.

137. Moreover, as discussed below, Defendants made materially false statements and material omissions with respect to internal and FDA concerns that the mineral oil placebo was not inert and distorted the ANCHOR test results, and that the JELIS study could be considered comparable to REDUCE-IT.

138. The underlined quotations in paragraphs 184 through 381, and other paragraphs referenced herein, were materially false or misleading when made, and/or omitted material information necessary to make the statements not misleading under the circumstances in which they were made for the following reasons:

(i) Statements that the results of the long-term REDUCE-IT CVOT were not required for FDA approval of the ANCHOR indication, when in fact the FDA had stated that whether the REDUCE-IT results would be required was a "review issue," and given the failure of the ACCORD and AIM-HIGH trials, were almost certainly going to be required by the FDA prior to approval of ANCHOR (¶¶ 191, 229, 234, 235, 241, 245, 252, 259, 272, 288, 301, 303, 354, 374, 381).

(ii) Statements that the July 6, 2009 SPA only required completion of the MARINE and ANCHOR studies and that the long-term REDUCE-IT CVOT be "substantially underway" for filing of the ANCHOR sNDA, when in fact the FDA had advised Amarin that there was a lack of substantial scientific proof supporting the ANCHOR surrogate end-point study, and that the ANCHOR SPA were only "minimum" requirements and that acceptance of the ANCHOR sNDA would be a review issue (¶¶ 229, 234, 241, 242, 245, 259, 262, 267, 272, 282, 288, 291, 294, 296, 297, 301, 302, 305, 306, 307, 310, 312, 315, 324, 332, 335, 352, 353, 381).

(iii) Statements that Amarin had reached an agreement with the FDA on the analysis of the ANCHOR study, that the FDA was receptive to TG lowering as a surrogate endpoint, when in fact Amarin has admitted its actual knowledge of the FDA's "substantial uncertainties," with respect to Amarin's purported scientific evidence supporting the ANCHOR sNDA (¶¶ 187, 189, 193, 287, 311, 322, 323, 324, 325, 336, 358, 359, 379, 381).

(iv) Statements that reduction of TGs was an accepted surrogate for the reduction of CVD (¶¶ 185, 189, 191, 192, 194, 240, 241, 258, 261, 270, 284, 286, 298, 313, 331).

(v) Statements that the failure of the ACCORD and AIM-HIGH trials were a competitive advantage because Vascepa was neither a fibrate nor niacin (¶¶ 124, 381).

(vi) Statements that Vascepa was "designed to be first in class" for the treatment of high triglycerides, for all the foregoing reasons stated above (¶¶ 218, 295, 224, 233, 242, 253, 269, 283, 294, 360, 367).

(vii) Statements that the positive ANCHOR results "will stimulate additional interest from commercial partners." Those "commercial partners" would certainly have reviewed the regulatory record prior to committing resources to Amarin, and having done so, would recognize that approval of the ANCHOR indication would require the completion of the REDUCE-IT study, and would be dissuaded from investing in Amarin (¶¶ 229, 260).

(viii) Statements of the anticipated 36 million patient population for Amarin, for all the foregoing reasons stated above (¶¶ 217, 218, 220, 224, 257, 283, 285, 295, 297, 298, 349, 350, 352, 357, 380, 381).

139. Each of those statements was materially false and misleading and omitted materially facts for the reasons stated above concerning (i) the July 14, 2008 FDA meeting and Minutes, (ii) the July 6, 2009 ANCHOR SPA, (iii) the March 14, 2011 teleconference between the FDA and Amarin, and (iv) the August 5, 2011 REDUCE-IT SPA, and as confirmed by the parties in correspondence dated November 7, 2013 (Ketchum to FDA), February 27, 2014 (Ketchum to FDA), April 22, 2014 (Rosebraugh to Amarin), May 22, 2014 (Ketchum to FDA), and September 11, 2014 (Jenkins to Amarin), and the FDA and members of the Advisory Committee in the FDA's October 11, 2013 Briefing Document and the October 16, 2013 Hearing.

140. At a meeting with the FDA in July 2008, representatives of Amarin were informed by the FDA that there were no existing long-term studies that established that the introduction of a second drug for the treatment of TGs (such as Vascepa) as an adjunct to a statin significantly reduced cardiovascular risk, and that the ongoing ACCORD-Lipid and AIM-HIGH studies (and other TG-reducing outcomes studies) would be influential to the FDA's willingness to approve Vascepa for the ANCHOR indication only on the basis of a surrogate endpoint. The information provided by the FDA at that meeting was reflected in the minutes of that meeting provided by the FDA to Amarin. The FDA had only agreed in the July 6, 2009 and August 5, 2011 SPAs that the "**minimum**" requirements for filing the NDA did not require the completion of the outcomes (REDUCE-IT) study and that the FDA had not yet determined whether the results of the outcomes study would be required for FDA approval of the ANCHOR

indication. By at least March 14, 2010, Defendants (other than Defendant Ketchum who joined Amarin in February 2012) were aware of the negative results of the ACCORD-Lipid trial and by at least May 26, 2011, Defendants (other than Defendant Ketchum) were aware of the negative results of the AIM-HIGH trial when it was announced that AIM-HIGH was discontinued. When Defendants choose to speak about the procedures, prospects, or potential market size for obtaining FDA approval to market Vascepa for the ANCHOR indication, they had an obligation to disclose the whole truth, including the FDA's substantial articulated concern with approving Vascepa for the ANCHOR indication based only on the ANCHOR trial. The FDA's articulated concerns with the ANCHOR trial made it substantially less likely that the FDA would approve the ANCHOR indication prior to the completion of the REDUCE-IT trial than would have been apparent to a reasonable investor based only on the information publicly disclosed by Defendants.

141. The statements highlighted in ¶¶ 184, 236, 238, 292, 361, 381 that represented that the JELIS study was indicative of efficacy of Vascepa for the ANCHOR indication were materially false and misleading because they failed to disclose material distinctions with respect to JELIS. Defendants were aware of the distinctions between JELIS and ANCHOR and knew that the results of the JELIS study (high LDL-C at baseline and low statin administration) were not indicative of efficacy of Vascepa for the ANCHOR indication. When Defendants choose to speak about the JELIS study, they had an obligation to disclose the whole truth, including that the results of the JELIS study (high LDL-C at baseline and low statin administration) were not indicative of efficacy of Vascepa for the ANCHOR indication. The lack of relevance of the JELIS study to ANCHOR's sNDA made it substantially less likely that the FDA would approve the ANCHOR indication based only on the ANCHOR study than would have been apparent to a

reasonable investor based only on the information publicly disclosed by Defendants.

142. The statements highlighted in ¶¶ 215, 253, 266, 268, 269, 285, 292, 297, 313, 334, 348, 351, 352, 358, 359 that (i) the use of mineral oil as a placebo did not raise any specific concerns with respect to the anticipated approval of the ANCHOR sNDA by late 2013, and (ii) that the ANCHOR study achieved its primary and secondary endpoints, were materially false and misleading for reasons relating to Amarin's use of mineral oil as a placebo. Beginning at least as early as April 18, 2011, when the ANCHOR test results were first disseminated, Defendants had actual knowledge that mineral oil may not be inert. According to the FDA's statements at the Advisory Committee Meeting, the FDA's with the use of mineral oil as placebo was shared with Amarin prior to the AdCom. When Defendants choose to speak about the ANCHOR study, they had an obligation to disclose the whole truth, including the FDA's and Amarin's senior officers' concerns that mineral oil was not inert. The concern with respect to mineral oil as a placebo made it substantially less likely that the FDA would approve the ANCHOR indication based only on the ANCHOR study than would have been apparent to a reasonable investor based only on the information publicly disclosed by Defendants.

143. Each of Defendants Amarin, Zakrzewski and Thero are responsible for the Company's statements and their own statements throughout the Class Period. Defendant Ketchum is responsible for the Company's statements and his own statements upon joining Amarin in February 2012. Amarin is also responsible for the false statements made by its senior officers, including Declan Doogan and Paresh Soni, made within the scope of their employment.

144. The actual knowledge of Declan Doogan gained by virtue of his participation at the July 14, 2008 FDA meeting in his capacity as Amarin's Chief Medical Officer is attributable

to Amarin under the concept of corporate scienter.

B. The November 29, 2010 Press Release and Presentation

145. On November 29, 2010, prior to the opening of the U.S. securities markets, Amarin issued a press release announcing "positive, statistically significant top-line results from the MARINE Study, its first Phase III clinical trial of lead drug candidate Vascepa."

146. The November 29, 2010 press release quoted Joseph S. Zakrzewski as stating:

> Furthermore, the MARINE study results are encouraging, especially the positive outcomes with respect to LDL-C and other lipids, as we await the results of the ongoing ANCHOR study. This separate Phase III study is designed to investigate [Vascepa] in patients with high triglycerides (>200 and <500mg/dL) mixed dyslipidemia treated with statins, a patient population for which no drug in this class is currently approved. While the market for a drug labeled for treatment of triglycerides of > 500mg/dL is already proven to be a billion dollar market, there are ten times the number of patients with triglycerides of >200 and <500 mg/dL. [Emphasis added.]

147. On a conference call conducted on November 29, 2010, Defendants emphasized in prepared remarks the far greater commercial opportunity from ANCHOR (than MARINE):

> I'd like to mention that [Vascepa] is also being studied in a second, different population; that is the ANCHOR study. This study consists of patients with high triglyceride levels between 200 mg/dL and 500 mg/dL who are all on stable statin therapy for elevated LDL-C. In the U.S. no prescription omega-3 is presently approved for treating this patient population, which includes 36 million patients…. In this larger population of patients with high triglycerides, we seek to be first in class with [Vascepa]. [Emphasis added.]

148. Present on that conference call were Defendants Zakrzewski and Thero. The foregoing statements were materially false and misleading because when Defendants chose to speak on the subject of ANCHOR, they had an obligation to disclose the entire truth, including the contradictory fact that the FDA had already informed Amarin that the ACCORD-Lipid and AIM-HIGH trials would be indicative of whether an outcomes trial would be necessary, and ACCORD-Lipid had already been reported to be a failure.

149. A presentation published in association with the announcement of the results of the MARINE Study (available on Amarin's website) referred to "Large Underpenetrated Market Opportunities," including a market of 36 million people (with triglyceride levels of 200-499 mg/dL) for the ANCHOR indication and 34 million people (with triglyceride levels of 150-199 mg/dL) in a category described as "Future Potential." Emphasis added.

150. On the announcement, Amarin's stock prior increased $2.30 per share to close on November 29, 2010 at $5.85 per share (a 64.8% increase), with extremely high trading volume of 43.9 million shares traded.

151. The market understood the Company's statements regarding the MARINE results to bode well for ANCHOR prospects. A November 30, 2010, Canaccord Genuity Daily Letter stated a "buy" recommendation including the following:

> We think MARINE data bodes well for Q2/11 ANCHOR data; raising target from $7 to $9 on increased chances of FDA approval. [Vascepa] is AMRN's purified EPA omega-3 drug for high triglycerides. We expect release of very positive complete MARINE data and top-line ANCHOR pivotal trial data in H1/11. We think AMRN may submit the [Vascepa] NDA for very high triglycerides in mid-2011 and get approval in H1/12. Our new $9 target is based on a revised NPV analysis. [Emphasis added.]

C. The December 16, 2010 Press Release

152. On December 16, 2010, prior to the opening of the U.S. securities markets, Amarin issued a press release reporting "the completion of patient randomization for its ANCHOR trial, a pivotal Phase III trial of [Vascepa]. The Company indicated that it anticipates reporting top-line results from this trial in Q2 2011 (the Company's previous guidance for the timing of such results was mid-2011)."

153. The press release quoted Defendant Zakrzewski stating, "[w]e are pleased that the ANCHOR study has been able to complete the patient randomization process before the end

of 2010," and further "[f]ollowing the very positive results of the recently reported MARINE study in which [Vascepa] demonstrated that it reduced triglyceride levels without increasing LDL-C in patients with very high triglycerides (>500 mg/dL), the ANCHOR study evaluates [Vascepa] in a different and larger patient population. [Vascepa] is designed to be first-in-class for this indication. In the U.S. alone, there are 36 million patients with triglyceride levels in the range being studied in the ANCHOR trial." [Emphasis added.]

154. Following the press release on December 16, 2010, the price of Amarin shares increased to close at $6.35 up from $6.29.

D. The January 5, 2011 Offering Announcement

155. As of January 2011, Amarin did not have sufficient cash on hand to complete the REDUCE-IT outcomes study. Defendants also knew that the market for the MARINE indication of Vascepa would not yield sufficient cash to fund the REDUCE-IT study such that Defendants needed to sell Amarin shares in a public offering.

156. By January 2011, Defendants had sufficiently hyped the market for the ANCHOR indication of Vascepa and its prospects for FDA approval that the well of enthusiastic investors was primed for a secondary offering.

157. On January 5, 2011, prior to the opening of the U.S. securities markets, Amarin announced in a press release "that it intends to offer for sale its American Depositary Shares in an underwritten public offering. Jefferies & Company, Inc. and Leerink Swann LLC are acting as joint book-running managers in the offering, and Canaccord Genuity Inc. is acting as co-lead manager for the offering."

E. The January 6, 2011 Prospectus Supplement

158. On January 6, 2011 Amarin issued a Prospectus Supplement on Form 424B5 for

an offering of 12 million American Depositary Shares at a price to the public of $7.60 per ADS. "In addition, under the terms of the Underwriting Agreement, [Amarin] granted the Underwriters an option, exercisable for 30 days, to purchase up to an additional 1,800,000 ADSs solely to cover over-allotments, if any." The Prospectus Supplement stated, among other things:

> In order to obtain a separate indication for Vascepa based on the ANCHOR trial results, the Food and Drug Administration, or FDA, requires that we have a clinical "outcomes study" substantially underway at the time of filing a New Drug Application, or NDA. If we elect to seek this separate indication in our initial NDA filing and commence an outcomes study, we will need to seek additional financing, through a commercial partner or otherwise. The results of an outcomes study are not required for FDA approval of the broader indication, and an outcomes study is not required for the indication being studied in the MARINE trial. [Emphasis added.]

159. Defendants Zakrzewski and Thero signed the Underwriting Agreement on the 2011 offering, which was part of an 8-K filed with the SEC on January 6, 2011. They allowed the false statements to be issued in the Prospectus Supplement.

160. Following the January 6, 2011 pricing announcement and supplement publication, shares of Amarin increased in price by 11.1% to $8.59 on volume of 9.6 million.

161. Pursuant to the Supplement, Amarin sold 13.8 million ADSs for a total of approximately $98.7 million in proceeds, net of fees and transaction costs (inclusive of the underwriters' over-allotment option).

F. The 2010 Form 10-K

162. On March 16, 2011, Amarin filed its Form 10-K for the period ending December 31, 2010. In a press release announcing the results, Defendant Zakrzewski was quoted, stating, in part:

> Among prescription Omega-3 based drugs, [Vascepa] has the potential to be best-in-class for treating patients with very high triglycerides and the first-in-

> class for treating patients with high triglycerides with mixed dyslipidemia. Our focus is to become the leader in the market for triglyceride-lowering drugs by providing clinicians and patients a new generation of prescription Omega-3 therapies that offer a superior efficacy and safety for individuals who also suffer from other cardiovascular risk factors, including elevated non-HDL cholesterol levels. [Emphasis added.]

163. The Form 10-K stated, "[i]n order to obtain a separate indication for Vascepa based on the ANCHOR trial results, the FDA requires that we have a clinical outcomes study substantially underway at the time of the NDA filing. The results of an outcomes study are not required for FDA approval of the broader indication." (at 3 and 4). [Emphasis added.]

164. In further describing the ANCHOR trial, the Form 10-K reiterated, "[i]n order to seek approval of this potentially expanded indication, we will be required to have substantially enrolled subjects in a medical outcomes study at the time of our NDA submission. We are in the process of defining the clinical trial design for the outcomes study. We do not anticipate initiating the outcomes study until after the ANCHOR trial is complete. The results of this outcomes study are not required for approval of the indication studied in the ANCHOR trial; the only requirement is that the outcomes study is substantially underway." (at 6, 11, 39 and 41). [Emphasis added.]

165. The 10-K (at page 6) also discussed JELIS as establishing a successful outcomes study for the ANCHOR indication of Vascepa:

> Among the reasons why Phase II trials were not conducted or required is that the active ingredient in Vascepa, ethyl-EPA of not less than 96% purity with no DHA, has been approved by regulatory authorities in Japan and marketed by Mochida Pharmaceutical Co. for over a decade. In Japan, ethyl-EPA is marketed under the product name of Epadel and is indicated for hyperlipidemia and peripheral vascular disease and which we understand has 2009 revenues in Japan that exceed $500 million per year. Clinical data from Japan shows that Epadel is effective in reducing TGs. In addition, in an outcomes study called the Japan EPA Lipid Intervention Study or JELIS Study (JELIS), which study consisted of more than 18,000 patients followed over multiple years, Epadel, when used in conjunction with statins, was shown to reduce cardiovascular events by 19%

> compared to the use of statins alone. In this study, cardiovascular events decreased by approximately 53% compared to statins alone in the subset of patients with triglyceride levels of 150 mg/dL (average 269 mg/dL at entry) and HDL-C <40 mg/dL. [Emphasis added.]

166. Defendants Zakrzewski and Thero signed the March 16, 2011 Form 10-K, certifying, among other things, the truth of the Form 10-K.

167. The exact same or substantially similar representations with respect to JELIS were made in Amarin's Form 10-Ks for the period ended December 31, 2011 at page 9 (filed with the SEC on February 29, 2012) and for the period ended December 31, 2012 at page 8 (filed with the SEC on February 28, 2013).

G. The March 17, 2011 Conference Call

168. On March 17, 2011, Amarin conducted a conference call regarding fourth quarter 2010 earnings results. Defendants Zakrzewski and Thero were present on the call.

169. In his prepared remarks, defendant Zakrzewski stated on the call (at 3) that "[c]linical treatment guidelines recommend that patients with triglyceride level at or above 200 mgs per deciliter should be treated with a prescription triglyceride lowering therapy." [Emphasis added.]

170. On that call, Paresh Soni, Senior Vice President and Head of Development also emphasized that "[e]levated triglyceride levels are increasingly being recognized as a significant modifiable risk factor for cardiovascular disease alongside LDL-cholesterol." [Emphasis added.] Soni added that "[i]t's important to note that the results of the outcomes study are not needed in order to secure approval for the ANCHOR indication, but we do need to have this outcomes study well underway." [Emphasis added.]

171. Later on the call, Soni added, "[i]f the study is well underway and they are comfortable with our proposal, they will give us the indication." Emphasis added.

172. Soni joined Amarin in September 2008, within the months of the July 14, 2008 FDA meeting, and a year prior to the July 6, 2009 SPA. According to a September 17, 2008 press release announcing his Amarin employment, Soni had held "a number of leadership roles in Pfizer Global Research and Development" and had provided clinical leadership to a number of programs … including the submission of two New Drug Applications." Doogan as Interim Chief Executive Officer, was quoted in that press release as stating that Soni's "experience in progressing late stage programs through NDA filing will be an invaluable addition to our team."

173. Soni, by virtue of his senior role at Amarin, and his experience and sophistication, either had actual knowledge of the FDA minutes and July 6, 2009 SPA or was recklessly indifferent to the true facts of Amarin's Vascepa development.

174. During the Q&A portion of the call, Thomas Wei from Jefferies & Company requested clarification regarding the FDA's request that an outcomes study be substantially underway, to which Soni responded, "[t]hey have said to us that they do not need to see the data read out before they give us the indication that the ANCHOR study is positive. If the study is well underway and they are comfortable with our proposal, they will give us the indication." [Emphasis added.]

175. The statements attributed to Soni were made within the scope of Soni's employment by Amarin. Amarin is liable for the falsity of those public statements under the federal securities laws.

H. The April 14, 2011 FDA Teleconference

176. In an April 14, 2011 teleconference between the FDA and Amarin to discuss Amarin's proposed CVOT (REDUCE-IT), Amarin's representatives were informed "that for 'add-on to statin therapy' in subjects with TGs $\geq$ 200 and <500 mgl/dL, an Advisory Committee

meeting was likely before the indication could possibly be granted."

177. That reference to the conference call was contained in Minutes of a subsequent December 16, 2013 FDA meeting. The Minutes of the April 14, 2011 teleconference are not otherwise available.

178. The FDA's references that approval of Vascepa for the ANCHOR indication was only "possible" and that there was a need for an advisory committee meeting reflects the FDA's concern around the lack of substantial scientific evidence establishing the efficacy of Vascepa to reduce cardiac events.

I. The April 18, 2011 Press Release Announcing ANCHOR Trial Results

179. On April 18, 2011, prior to the opening of the U.S. securities markets, Amarin released results from the ANCHOR trial and the price of Amarin ADSs surged 95% from a close of $8.77 the prior trading day to $17.10 (a 95% increase). Reported trading volume was 53.5 million shares.

180. According to the release,"[t]he purpose of the ANCHOR trial was to demonstrate that [Vascepa] is effective in reducing triglyceride levels in patients with high triglycerides without increasing LDL-C ("bad cholesterol") levels in patients on background statin therapy. The ANCHOR trial investigated [Vascepa] as a treatment for high triglycerides (≥200 and <500mg/dL) in 702 patients with mixed dyslipidemia (two or more lipid disorders) on background statin therapy…." The press release reported that the Company had observed "positive, statistically significant top-line results from its ANCHOR trial for [Vascepa]. The Phase 3 trial met its primary and secondary efficacy endpoints for both the 4 gram and 2 gram daily doses." [Emphasis added.]

181. The April 18, 2011 press release also contained the following additional

materially false and misleading statement that "the results of an outcomes study are not required for FDA approval of the broader [ANCHOR] indication…." [Emphasis added.]

182. In addition the April 18, 2011 press release contained the following materially false and misleading statement attributed to defendant Zakrzewski: "The ANCHOR trial results are even more remarkable than the broadly positive MARINE trial results. We believe these results clearly differentiate [Vascepa] from other triglyceride lowering therapies and position [Vascepa] to be both first-in-class and best overall therapy for treating the high triglyceride population." [Emphasis added.]

183. The April 18, 2011 press release contained the following materially false and misleading statements with respect to the "reduction of LDL-C by 6.2% from baseline versus placebo." [Emphasis added]. In fact, those test results raised internal concerns at Amarin and with the FDA, not expressed in the press release or at any time during the Class Period by defendants, that the ANCHOR test results indicated that mineral oil was not inert and had an adverse affect on absorption of the statin in the control group.

184. Defendants' statements in the April 18, 2011 press release were further materially false and misleading because Defendants failed to reveal the FDA's stated concern that success in the ANCHOR study would not necessarily be indicative of an outcomes benefit, and depending on the results of the ACCORD-Lipid and AIM-HIGH and other outcomes studies, the completion of the REDUCE-IT trial was likely to be required prior to FDA approval of the ANCHOR indication.

J. The April 18, 2011 Conference Call

185. The Company also conducted a conference call in conjunction with the Phase III Trial Results.

186. Defendant Zakrzewski said that "[o]n the basis of the MARINE trial results alone, we believe that Vascepa is positioned to become a billion dollar worldwide marketed product[]. We believe that ANCHOR results expand this opportunity multiple fold." [Emphasis added.]

187. Zakrzewski added on the conference call that:

> therapies [that] are reducing cardiovascular risk are the multi-dimensional, targeting a broader set of lipid biomarkers, not only LDL-C. With these positive results, Amarin will continue to move aggressively forward to NDA submission and with commercialization plans for AMR101. [Emphasis added.]

188. Defendant Thero added, "[r]ecall that under the terms of the special protocol assessment agreement we have with the FDA in order to file an NDA seeking approval for the [ ] treatment of patients with high triglyceride with mixed dyslipidemia, the indication [] studied in the ANCHOR trial, we must have a clinical outcomes study substantially underway, but not complete at the time of the NDA submission." [Emphasis added.]

189. Thero also stated that:

> We anticipate that the positive ANCHOR results will stimulate additional interest from potential commercial partners. [G]iven the strongly positive nature of the ANCHOR results, we anticipate that the pace of such discussions may accelerate, and together with our advisors, we are taking steps to accelerate such discussions. [Emphasis added.]

190. When asked during the Q&A portion if there is any reason that this would not produce an outcomes benefit, Soni stated (notwithstanding the unsuccessful completion of the ACCORD-Lipid trial), "the short answer to your question [] is basically, no. … I don't see any potential reason that in outcomes that it will not be positive." [Emphasis added.]

191. Zakrzewski added, "[f]or ANCHOR, we have that substantially underway as we talked about. The FDA has signaled to us that, is that 25% of the patients, is that 50% of the patients enrolled. What I was trying to signal on the past discussions, or on the past calls are,

because of the data we're seeing and because of the dialogues that we're having with the agency, there are possibilities that it could be negotiated differently. … If you take it at its face value, it's probably a quarter to half the patients prior to a formal submission."

192. Zakrzewski's statement that "it's probably a quarter to half the patients prior to a formal submission" was materially and knowingly false in that the July 6, 2009 SPA clearly stated that 50% of patients needed to be enrolled in REDUCE-IT before the FDA would accept the ANCHOR sNDA for filing.

193. Those statements on the April 18, 2011 conference call were materially false because defendants' failure to disclose the FDA's acknowledged "substantial uncertainties" around TG as a surrogate for CV risk, that AIM-HIGH and ACCORD would provide "important information" with respect to that issue, that AIM-HIGH and ACCORD did not evidence that reduction of TGs would result in improved CV health, and that in light of the foregoing the FDA was likely to require the completion of the REDUCE-IT study prior to approval of Vascepa for the ANCHOR indication.

194. Each of the foregoing omitted facts would have been significant to a reasonable investor in making an investment decisions.

K. The May 10, 2011 Press Release Announcing First Quarter 2011 Operating Results

195. On May 10, 2011, prior to the opening of the U.S. securities markets, Amarin reported First Quarter results for 2011. In the press release, Amarin reiterated the "positive ANCHOR trial results" and "successful" MARINE clinical trial. [Emphasis added.]

196. The press release stated further that "[i]n order to secure an indication based on the ANCHOR trial results, a supplemental NDA for the ANCHOR trial results will likely be submitted upon substantial enrollment of patients in an outcomes study, the design of which is

near completion." [Emphasis added.]

197. The press release also quoted Zakrzewski stating "[w]ith the highly successful results from the ANCHOR and MARINE Phase III trials in hand, we are rapidly advancing our business plan to maximize the value of Vascepa through commercial preparations that include regulatory, supply chain and sales and marketing initiatives.… [Emphasis added.]

L. The May 10, 2011 Conference Call

198. During the First Quarter 2011 earnings call, Zakrzewski stated that "[w]hile the results of the MARINE trial as announced nearly six months ago were impressive, the ANCHOR trial results were even more significant, as we believe those results position Vascepa to be the first-in-class drug approved for use in the large mixed-dyslipidemia market, with Vascepa having successfully achieved or exceeded all primary and secondary endpoints of the ANCHOR trial." [Emphasis added.]

199. Defendant Zakrzewski stated, in prepared remarks, on the conference call that the "ANCHOR trial's primary endpoint was a statistically significant reduction in trigs compared to placebo. Secondary endpoints were non-inferiority regarding LDL-C as compared to placebo as well as statistically significant reduction in non-HDL-C, Apo B, Lp-PLA2 and VLDL-C compared to placebo." Zakrzewski added that "[a]ll of these biomarkers are important risk factors for cardiovascular disease." [Emphasis added.]

200. In the context in which this statement was made, a reasonable investor would have wanted to know the contrary fact that the FDA had advised Amarin in July 2008 that "we are not aware of any prospective, controlled clinical trial data demonstrating that pharmacologic reduction of non-HDL-C (or TG) with a second drug in patients with elevated TG levels at LDL goal on statin therapy significantly reduces the residual risk for CVD."

201. Thus, it was the FDA's opinion as of May 10, 2011 that there was a lack of substantial scientific evidence that a reduction in "these biomarkers," including FGs, "are an important risk factor for cardiovascular disease." Zakrzewski, on the conference call, went on to discuss plans for submitting the MARINE NDA and referenced ANCHOR stating that "[a]n outcomes study must be substantially enrolled, but results are not required in order to secure approval of an indication based on the ANCHOR trial results." Emphasis added.

202. Following the May 10, 2011 press release and investor call, the price of Amarin ADSs increased to close at $16.83 from a closing price of $16.34 on the prior trading day.

M. AIM-HIGH Trial Discontinued

203. On May 26, 2011, the National Heart Lung and Blood Institute (NHLBI), which sponsored the AIM-HIGH study, announced that the study had been halted 18 months ahead of schedule because there was no incremental clinical benefit from the addition of niacin to statin therapy during a 36-month follow-up period, despite significant improvements in HDL cholesterol and triglyceride levels. Complete results were later published on December 15, 2011 in The New England Journal of Medicine.

204. Because Defendants systematically failed to disclose the truth about the importance to the FDA of the ACCORD and AIM-HIGH study results, the market failed to appreciate the significance of the AIM-HIGH failure on Amarin and its prospects for approval of the ANCHOR indication.

205. For example, on May 26, 2011, Jefferies & Company, Inc. published a Company Note on Amarin with a "buy" recommendation and a price target of $25.00, stating, among other things that the failure of the AIM-HIGH study had positive implications for Amarin:

> Our Take: Incremental Positive For [Vascepa]. Overall, we see today's news as a positive for AMRN. If AMRN's proposed CV outcomes study is positive, [Vascepa] would then become the only triglyceride lowering therapy in the U.S. with a CV benefit, with niacin's failure in AIM-HIGH paving the way for significant market share gains by the omega-3 class. In addition, we believe that the stroke issue observed with niacin in the AIM-HIGH study is not likely to be an issue with [Vascepa], as the evidence on EPA suggests an anti-coagulant effect (see p2) and no increase in strokes was observed in the JELIS study (1.7% control vs. 1.8% EPA). While the failure of AIM-HIGH, in combination with data from ACCORD-LIPID and FIELD, raises questions on whether triglyceride lowering confers a benefit on CV outcomes, we continue to believe that [Vascepa] may still show a CV outcomes benefit due to its differentiated lipid lowering profile and the 19% reduction in CV events observed in the Japanese JELIS study with what is effectively a low dose version of [Vascepa]. AMRN expects to begin enrollment of its CV outcomes study in 2H11.

206. Had Defendants disclosed the truth regarding the FDA's position on ACCORD and AIM-HIGH and JELIS, the market would have understood that a negative AIM-HIGH result increased the likelihood that the FDA would deny the sNDA for the ANCHOR indication of Vascepa subject to the successful completion of the REDUCE-IT study.

N. The August 5, 2011 REDUCE-IT SPA Further Confirms that Approval of the ANCHOR Indication Would Be a Review Issue

207. An August 5, 2011 SPA between Amarin and the FDA, for the REDUCE-IT study, further confirms that the FDA was not obligated to approve Vascepa for the ANCHOR indication based only on proof of efficacy in the ANCHOR trial and 50% or more enrollment in REDUCE-IT. Rather, Amarin Question and FDA Response No. 2 states:

> 2. Have we reached agreement on the design and size of this study Protocol AMR-01-01-0019 that, prior to completion, will support the indication (to be applied for with adequate results from the study AMR-01-01-0017; SPA agreement 06 July 2009 and approximately 50% enrollment in REDUCE-IT) as an adjunct to diet to reduce TG levels in patients with high (> 200 mg/dL) TG levels not controlled by diet or statin therapy?
>
> **FDA Response: The approvability of the indication will be a review issue. [Emphasis in the original.] [NY Dkt. No. 53-5]**

208. Thus, whether the REDUCE-IT CVOT would be required to be completed prior

to FDA approval of Vascepa for the ANCHOR indication had not been determined but was known to Amarin, to be a "review issue." That the FDA stated in the July 6, 2009 and August 5, 2011 SPAs that the ultimate approval of the ANCHOR indication was a "review issue" clearly related to its earlier advice to Amarin of the implication of AIM-HIGH and ACCORD on the ANCHOR sNDA.

209. It would be the hallmark of reckless indifference for Amarin and the Individual Defendants not to have drawn a connection between the FDA's comments at the July 2008 meeting and the limitations in the August 5, 2011 SPA.

O. The August 9, 2011 Press Release

210. On August 9, 2011, after the close of the U.S. securities markets, Amarin reported financial results for the second quarter of 2011.

211. The August 9, 2011 press release contained the following materially false and misleading statement: **"**As previously described, and in accordance with the Special Protocol Assessment (SPA) agreement for the ANCHOR trial, in order to request approval for an indication based on the ANCHOR trial results - reduction in triglycerides in patients with high triglycerides (≥200 and <500mg/dL) who are also on statin therapy for elevated LDL-cholesterol levels- a cardiovascular outcomes study must be substantially underway." [Emphasis added.]

212. The press release also contained the following materially false and misleading statement that: "[t]he Company believes that the treatment of high triglycerides in patients on statins represents a major commercial opportunity for [Vascepa] as a potential first-in-class prescription medicine for this indication."

213. In addition, the August 9, 2011 press release contained the following materially

false and misleading statement attributed to defendant Zakrzewski: "We believe that [Vascepa] is well positioned to be a catalyst in an emerging paradigm shift toward the increased treatment of lipid levels separate from and in addition to cholesterol management to reduce residual cardiovascular risk." [Emphasis added.]

P. The August 10, 2011 Earnings Call

214. During a conference call on August 10, 2011, in conjunction with Second Quarter 2011 financial results, conducted beginning at 8:00 a.m. EDT, Zakrzewski said "[s]ince our last quarterly update, we achieved a number of key objectives, including completion of the ANCHOR trial, a pivotal Phase III study of Vascepa in patients with high triglycerides and mixed dyslipidemia, in which all primary and secondary endpoints were achieved. …" He also stated that "[b]oth indications studied in the ANCHOR and MARINE trials represent potential multi-billion dollar opportunities …" [Emphasis added.]

215. Zakrzewski added that:

> Clinical treatment recommend that such patients [with TG levels greater than >200 mg/dL] be treated with diet and triglyceride-lowering therapy.... We believe that AMR101, due to its demonstrated product profile of reducing triglycerides, not increasing LDL-C, and excellent safety profile, will compete effectively with these kind of therapies and, more importantly, support market penetration and expansion well beyond current levels. [Emphasis added.]

216. Zakrzewski also stated that there were prospects for the FDA to approve ANCHOR at the same time as it approved MARINE: "[w]e also hope that as we submit all the data in September [2001], by the time we actually have the so-quote substantial enrollment, the FDA will be impacted positively to say, ah, you have met the criteria. We'll give you both indications simultaneously."

217. Paresh Soni spoke in more detail stating that "[t]he trial design and SPA position us to move forward aggressively with the outcomes study, not only in support of the indication

studies in the ANCHOR trial, but also for pursuit of a potential label expansion for Vascepa. As many of you know, Amarin is planning to have a cardiovascular outcomes study substantially underway, but not completed in order to pursue the indication studies in the ANCHOR trials. … The trial is designed to assess whether Vascepa is able to reduce the residual cardiovascular risk that remains after statin therapy." [Emphasis added.]

Q. The August 10, 2011 Press Release

218. Also on August 10, 2011, prior to the opening of the U.S. securities markets, Amarin issued a press release advising investors that it had "reached agreement with the FDA on a Special Protocol Assessment (SPA) agreement for the design of the previously described cardiovascular outcomes study of [Vascepa] formally titled REDUCE-IT."

219. The August 10 press release estimated that the REDUCE-IT study "will require approximately 8,000 patients and take approximately 6 years for completion. The Company anticipates that if, as intended, it commences Outcomes study activities in 2011 that it will be positioned to achieve approximately 50% enrollment before the end of 2012."

220. The August 10 press release contained the following materially false and misleading statement: "Once REDUCE-IT is substantially underway, the Company believes that it will have met all of the requirements to request approval of [Vascepa] for treating the mixed dyslipidemia patient population studied in the ANCHOR trial." [Emphasis added.]

221. The August 10 press release quoted defendant Zakrzewski as making the further materially false and misleading statement: "Based on the strong safety profile of [Vascepa], our positive Phase 3 results for [Vascepa] and success in Japan with an outcomes study of highly pure EPA, we believe that REDUCE-IT is positioned for success." [Emphasis added.]

R. The November 7, 2011 Press Release

222. On November 7, 2011, prior to the opening of the U.S. securities markets, Amarin reported Third Quarter results for 2011. In the press release announcement, the Company announced that it had submitted the NDA to the FDA requesting approval of Vascepa for the MARINE indication.

223. Amarin also included a "Clinical Update" on the REDUCE-IT Outcomes Study, including the representation that "[o]nce REDUCE-IT is substantially underway, the Company believes that it will have met all of the requirements to request approval of Vascepa for treating the mixed dyslipidemia patient population studied in the ANCHOR trial. Vascepa is positioned to be the first drug in its class approved for treatment of this indication." [Emphasis added.]

224. The release further stated, "The Company believes that Vascepa represents a major commercial opportunity as it is estimated approximately 4 million people with very high triglyceride levels (≥500mg/dL-the triglyceride range studied in the MARINE trial) and approximately 36 million people with high triglyceride levels (>200 and < 500mg/dL) – the triglyceride range studied in the ANCHOR trial and a potential first in class prescription medicine for this indication)."

S. November 8, 2011 Earnings Call

225. On November 8, 2011, prior to the opening of the U.S. securities markets, Amarin hosted a conference call to discuss the 2011 Third Quarter. During the call, Zakrzewski discussed REDUCE-IT, stating "On the ANCHOR application, the FDA has asked us to substantially enroll that study, the ANCHOR population by the end of next year. In fact, we believe what we are doing will more than be effective for accomplishing that goal." [Emphasis added.]

226. Zakrzewski went on to say that "[w]hile the population for the indications study in the MARINE trials is considered large, the indications studies in the ANCHOR trial represents a significantly larger opportunity as approximately 1 in 5 adults in the U.S. have triglycerides greater than 200 mg/dL. … We have not yet requested regulatory approval of the indication studied in the ANCHOR trial because the ANCHOR clinical trial results are included in our initial NDA submission. And because the efficacy and safety results of the study were favorable, we believe this indication will be well positioned for approval. While we cannot predict the timing of such approval, we note that supplemental approvals of [this] nature typically take less than half the time of an NDA to be approved." [Emphasis added.]

T. The January 3, 2012 Letter to Shareholders

227. On January 3, 2012, Amarin provided an overview of the Company's progress during 2011 in a letter to shareholders signed by Defendant Zakrzewski. Among other things, the letter reported the purportedly "Successful Clinical Trial Results" for MARINE and ANCHOR and stated, "[w]e believe Vascepa is well positioned to be an important part of the next generation in lipid management therapy. The indications associated with each of the MARINE and ANCHOR trials represent potentially large and clinically important markets, as approximately 1 in 50 adults in the United States alone have very high triglyceride levels (≥500 mg/dL) and approximately 1 in 5 adults in the United States have triglyceride levels ≥200 mg/dL." [Emphasis added.]

228. The January 3, 2012 letter was materially false and misleading because it failed to apprise investors that there was a substantial likelihood that the REDUCE-IT study would be required to be successfully completed prior to approval of the ANCHOR indicative.

U. The 2011 Form 10-K

229. On February 29, 2012, Amarin filed its Annual Report on Form 10-K for year ended December 31, 2011.

230. The 2011 Form 10-K stated "[t]o obtain FDA approval of [Vascepa] for the ANCHOR indication, based on communications with the FDA, we believe that we must first obtain approval of [Vascepa] in the MARINE indication and be substantially underway with a cardiovascular outcomes study at the time of the submission of an NDA to the FDA for the ANCHOR indication. Based upon feedback from the FDA and consistent with the respective SPAs for the MARINE trial and ANCHOR trial, we do not believe the final results of an outcomes study are required for FDA approval of [Vascepa] for either indication." [Emphasis added.]

231. Again the Company stated, "[c]onsistent with our SPA for the ANCHOR trial, we currently intend to file a supplemental NDA, or sNDA, seeking approval of the ANCHOR indication after the REDUCE-IT cardiovascular outcomes study is substantially underway. The sNDA cannot be filed until after both the initially submitted NDA for the indication studied in the MARINE trial is approved and the cardiovascular outcomes study is substantially underway." [Emphasis added.]

232. "Based upon feedback from the FDA and in accordance with the SPA for the ANCHOR study, we do not believe that the results of the REDUCE-IT outcomes study are required for approval of the indication studied in the ANCHOR trial." [Emphasis added.]

233. Defendants Zakrzewski and Thero signed the 2011 Form 10-K, certifying, among other things, the truth of the Form 10-K.

V. The February 29, 2012 Press Release

234. On February 29, 2012, prior to the opening of the U.S. securities markets, Amarin reported Fourth Quarter and Year End 2011 financial results and in the press release reiterated that "Amarin currently plans to file a supplemental NDA (sNDA) for the use of Vascepa in the treatment of patients with high triglyceride levels (≥200 and <500mg/dL) who are also on statin therapy for elevated low-density lipoprotein cholesterol, or LDL-C, levels (which the company refers to as mixed dyslipidemia), or what the company refers to as the ANCHOR indication. This population was studied in Amarin's ANCHOR Phase III trial. The sNDA cannot be submitted until after both the initially submitted NDA for the MARINE indication is approved and Amarin's cardiovascular outcomes study, REDUCE-IT, is substantially underway in the determination of the FDA. Each of the MARINE, ANCHOR and REDUCE-IT studies is the subject of a Special Protocol Assessment (SPA) agreement with the FDA." [Emphasis added.]

W. The February 29, 2012 Conference Call

235. On February 29, 2012, the Company hosted a Fourth Quarter Earnings Call during which Zakrzewski stated, "[w]e currently plan to file an sNDA for the high TGs mixed dyslipidemia indication studied in ANCHOR. That won't be filed until we have the [MARINE] approval and until we're substantially underway on the outcomes enrollment. On the outcomes enrollment, which again we do expect to be substantially underway by the end of 2012 and we have dosed the first patient at the end of '11. [W]e're currently working through a rolling process of clinical sites and activation." [Emphasis added.]

236. Among the items listed in the "2012 news flow," Zakrzewski included "[m]oving ahead on the outcomes study REDUCE-IT, this is going to be substantially underway, which

then will allow us to file the sNDA submission for the ANCHOR trial for mixed dyslipidemia." [Emphasis added.]

237. Analysts and media outlets continued to be deceived by Defendants' materially false and misleading public statements that the REDUCE-IT outcomes study was not required to be completed prior to FDA approval of Vascepa for the ANCHOR indication. A FirstWord Pharma ViewPoints article on March 7, 2012 stated, "[Vascepa] has delivered two sets of Phase III data that met efficacy endpoints (the MARINE and ANCHOR trials) and the FDA confirmed last month that it was not expecting to convene an advisory panel prior to the PDUFA date of July 26 [for MARINE]. Given the combination of efficacy data and its indication, Vascepa retains blockbuster potential, say analysts and Amarin."

X. The May 8, 2012 Press Release

238. On May 8, 2012, prior to the opening of the U.S. securities markets, Amarin announced financial results for the quarter ended March 31, 2012 and provided an update on company operations.

239. In the press release, among other things, the Company stated again that "Amarin currently plans to file a supplemental NDA (sNDA) for the use of Vascepa in the treatment of patients with high triglyceride levels (≥200 and < 500mg/dL) who are also on statin therapy for elevated low-density lipoprotein cholesterol, or LDL-C levels (mixed dyslipidemia), or what the company refers to as the ANCHOR indication. This population was studied in Amarin's ANCHOR Phase III trial. The sNDA for this indication can be submitted once the submitted NDA for the MARINE indication is approved and Amarin's cardiovascular outcomes study, REDUCE-IT, is substantially underway as determined by the FDA." [Emphasis added.]

240. The May 8, 2012 press release added that "[a]n SPA represents agreement

between the FDA and a company on the design and analysis of a clinical trial before it begins."

Y. The May 8, 2012 Conference Call

241. The Company also hosted a conference call in conjunction with the earnings announcement. Among other things, Zakrzewski said "our REDUCE-IT cardiovascular outcomes study, anticipated to last up to six years, is making good progress." He went on to say, "To go into a little more detail on regulatory status, our expectations are that Vascepa approval should come sometime in the second half of this year. Once approved for the very high triglyceride indications studied in the MARINE phase III trial, current plans are for Amarin to prepare to file our supplemental NDA, sNDA, for this high triglyceride/mixed dyslipidemic indications studied in the ANCHOR phase III trial. The sNDA can then be filed [when] Amarin's cardiovascular outcomes study, REDUCE-IT, is substantially underway." [Emphasis added.]

242. Zakrzewski also said, "[w]e are confident that VASCEPA's demonstrated ability in clinical trials to reduce triglycerides and work well as an add on to statin therapy positions the drug to not only compete for current patients, but to potentially address the unmet needs of the many patients with elevated triglycerides who are not currently receiving triglyceride lowering therapy, potentially expanding the market well beyond current levels." [Emphasis added.]

Z. Vascepa Is Approved for the MARINE Indication

243. On July 26, 2012, after the close of the U.S. securities markets, Amarin issued a press release announcing that it had received approval from the FDA to market and sell Vascepa capsules as an adjunct to diet to reduce triglyceride levels in adult patients with severe (TG $\geq$ 500mg/dL) hypertriglyceridemia (the MARINE indication).

244. During a conference call regarding the approval, Zakrzewski stated, "Now that the initial indication is approved, all that we see remaining prior to submitting an sNDA for the ANCHOR indication is the requirement of the cardiovascular outcomes study, REDUCE-IT, be substantially underway, which as we pretty recently expressed, we believe will occur before the end of 2012." [Emphasis added.]

245. Every FDA approved drug is accompanied by an FDA approved label that describes the attributes and effects of the drug for the benefit of physicians and patients. Although it is unlawful for a sponsor such as Amarin to market a drug such as Vascepa to physicians for off label use, such practices are in fact common. In any event it would not be unlawful for a physician to prescribe Vascepa to patients with mixed dyslipidemia notwithstanding that it is only FDA approved for patients with hypertriglyceridemia.

246. In fact, as part of the NDA for the MARINE indication, Amarin sought (unsuccessfully) to have the FDA approve adding the data from the ANCHOR trial to the MARINE label. Amarin's ostensible purpose for adding the ANCHOR test data to the MARINE label was to provide physicians and patients with more information with respect to Vascepa for the MARINE indication.

247. Although LOVAZA had been approved by the FDA for marketing to the MARINE population, it had never been tested for the ANCHOR population and its label contained no information with respect to any such indication.

248. Having the FDA approve adding ANCHOR data to the MARINE label was understood by investors to give Amarin a significant advantage over LOVAZA with respect to off-label use and was a significant indication whether the FDA would be likely to approve Vascepa for the ANCHOR indication.

249. Investors reasonably anticipated based on Defendants' public statements that the FDA would approve ANCHOR based only on surrogate endpoints, that the MARINE label would contain the ANCHOR efficacy data and that Amarin would achieve significant off-label sales prior to formal FDA approval of the ANCHOR indication.

250. In approving Vascepa for the MARINE indication, the FDA declined Amarin's request to include on the label details regarding the ANCHOR Phase 3 study results. This was a partial disclosure of the truth behind Amarin's false statements and indicated to investors the possibility that the FDA was less willing to approve Vascepa for the ANCHOR indication solely on the basis of the ANCHOR study, than otherwise believed.

251. Regarding the label, Zakrzewski stated, "[i]n terms of the ANCHOR data in or out, we couldn't be more delighted with this label. …. As we continue to dialog with the FDA, and again, we've got a great working relationship with them, we expect as we go through this process towards submission that we could see potentially other modifications to the label. Again, as we go through that, we'll see where it evolves to, but we believe very strongly that we are in a very good position." [Emphasis added.]

252. In response to a question whether another formal meeting would take place with the FDA regarding the ANCHOR indication "to actually talk about like a pre-submission meeting with them to confirm that all of the filing requirements, if you understand them, are still in place," Zakrzewski stated, "I think at this point, we've already had all the meetings we need to have with the FDA. We've got our pass through the FDA and we'll file the sNDA. And so clearly, we'll always be in good contact with the FDA, but there are no other formal meetings required before submitting the sNDA []." [Emphasis added.]

253. When asked about the differences between the SPAs [for MARINE and for

ANCHOR] and whether the Company feels "handicapped at all not having the ANCHOR data in the label," Zakrzewski stated that "the SPAs are different." He went on to explain, "the most important thing we've got to accomplish now, there were two things that we needed to submit the ANCHOR indication. Number one was MARINE approval and number two is to have the ANCHOR outcomes study, REDUCE-IT, substantially underway, which we continue to reiterate guidance that we should be there by the end of the this year and we expect to have that approved by the second half of next year." [Emphasis added.]

254. When asked further about the ANCHOR data on the MARINE label, among other things, Zakrzewski said, "we're going to have an indication we believe for ANCHOR for mixed dyslipidemia. … We think what's happening here is, the FDA likes our data, they like what we have and their answer is simply, let's get this right, let's get this indication approved as soon as we can and send you on your way. We'll give you the same ground and the MARINE indication that [GSK has], with the better Apo-B data, with the better LDL-C data, with all the other benefits around the safety profile and non-HDL-C. But let's get this data, the outcomes study underway, let's get it submitted and let's go about it in that way." [Emphasis added.]

255. On July 27, 2012, Amarin shares fell $1.81 per share, or 11.8%, to $13.51 a share, as a result of investor disappointment that the label approved by the FDA for marketing of Vascepa for the MARINE indication did not provide data on the Phase III test results from the ANCHOR study. 14.7 million shares were reported as trading on July 27, 2012.

256. Jon Lecroy an analyst with MKM Partners, was quoted on July 27, 2012 by Bloomberg News as stating that "[t]hey didn't get any of the ANCHOR trial data in the label, for patients with high triglycerides, which is a bigger patient population than the MARINE population they were approved for."

257. Before the securities markets opened on July 27, 2012, PropThink, an intelligence service that delivers long and short trading ideas to investors in the healthcare and life sciences sectors, issued a research report that relied on Defendants' fraudulent assurances with respect to the certainty of FDA approval of Vascepa for the ANCHOR indication. PropThink stated that "[t]he [FDA's] decision to expand the drug's market is expected before the end of the year, and with the initial approval obtained last night, the likelihood of a second approval is high."

258. The FDA's approval of MARINE should not have provided Defendants with further confidence that the FDA would approve ANCHOR. As the FDA stated at the October 16, 2013 Advisory Committee meeting (at 134), "the approval for severe hypertriglyceridemia [MARINE] should not be considered an endorsement that treatment is expected to reduce cardiovascular risk. Instead, the division has historically approved drugs for severe hypertriglyceridemia on the premise that treating severe elevations in trigylcerides would be expected to reduce the risk of acute pancreatitis."

AA. The August 8, 2012 Press Release

259. On August 8, 2012, Amarin reported Second Quarter 2012 Financial Results and provided an operations update, including a Vascepa regulatory update.

260. "Our recent progress has been broad and highlighted by our first U.S. marketing approval of Vascepa and continued progress toward protecting the commercial potential of Vascepa with additional patent protection," stated Joseph Zakrzewski, Amarin's Chairman and Chief Executive Officer. "We are now focused on our post-approval strategy for Vascepa. We are very pleased with the label for our initial approval and we continue to believe that Vascepa has the potential to redefine lipid management." [Emphasis added.]

261. The press release stated further, "[c]onsistent with prior guidance, Amarin plans to file a supplemental NDA (sNDA) for the use of Vascepa in the patient population studied in Amarin's ANCHOR Phase III trial. Prior to filing this sNDA, the FDA requires that Amarin's cardiovascular outcomes study, REDUCE-IT, be substantially underway."

BB. The August 8, 2012 Earnings Call

262. After the market closed on August 8, 2012, Amarin hosted a conference call in conjunction with Second Quarter 2012 earnings.

263. On that call, Zakrzewski stated "[w]e continue to communicate the exciting Phase III clinical data for MARINE and ANCHOR trials to the scientific community…."

264. He stated further that "[l]ooking ahead, now that Vascepa is approved for the initial indication, Amarin is preparing to file a supplementary NDA, an sNDA, for the high triglyceride mixed dyslipidemia indication studied in the ANCHOR Phase III trial. The sNDA can be filed when Amarin's cardiovascular outcomes study, REDUCE-IT, is substantially underway, which, as previously stated, we expect to achieve in 2012." [Emphasis added.]

265. During the Q&A portion of the call, a Jefferies analyst asked "[o]n the timing of filing the sNDA for ANCHOR, can you clarify how clear an understanding you have of the requirement to enroll in the outcomes study before filing? And again, I'm just trying to understand if there is some risk to delay from perhaps an incomplete understanding of the requirement." Zakrzewski responded, "What we've said and I think what we'll stick by is that we believe we'll have the approval in the second half of next year. And if you back that out to the maximum filing of a 10-month sNDA, that means we have to file no later than February 28, February 29, if it's a leap year. And I think we're well on track to do that and feel very comfortable continuing with that guidance." [Emphasis added.]

266. Following these statements, on August 9, 2012, the stock price of Amarin increased by 13.9% from a closing price the prior day of $11.34.

CC. The November 8, 2012 Conference Call

267. On November 8, 2012, at 4:30 p.m EST, the Company also hosted a conference call to discuss Third Quarter 2012 results.

268. During the question and answer portion of the call, Defendant Zakrzewski was asked by Chris Schott of JPMorgan about the rationale behind the use of mineral oil as a placebo in the MARINE and ANCHOR studies. Schott asked, "do you see your placebo choice as a marketing burden heading into the launch [of Vascepa]?"

269. Zakrzewski responded to shut down concerns about the placebo, stating, "[t]he FDA through our SPAs approved our placebo. And over the years, many companies have used olive oil, corn oil, mineral oil. We really think it's much to do about nothing, so we really don't see a difference."

270. Following the call, Amarin shares opened on November 9, 2012 at a price of $10.75 – up from a $10.26 close before the call.

DD. HPS2-THRIVE Trial Fails

271. On December 20, 2012, when Merck & Co., Inc., the HPS2-THRIVE study sponsor, issued a press release stating that the HPS2-THRIVE trial (testing the hypothesis that increased levels of HDL (good) cholesterol, would reduce the risk of serious adverse cardiovascular events) "did not significantly further reduce the risk of the combination of coronary deaths, non-fatal heart attacks, strokes or revascularizations compared to statin therapy."

272. More specifically, Merck revealed that the combination of extended-release

niacin and the antiflushing agent laropiprant failed to reduce the risk of major vascular events in patients with well controlled LDL-cholesterol levels.

273. The study was later presented at the American College of Cardiology 2013 Scientific Sessions in San Francisco, CA and is now published in the July 17, 2014 issue of The New England Journal of Medicine.

274. That HPS2-THRIVE failed to demonstrate that improved lipid management, in co-administration with a statin, reduced risk of a MACE, similar to ACCORD-Lipid and AIM-HIGH, created a further risk that the FDA would not approve Vascepa for the ANCHOR indication prior to the successful completion of the REDUCE-IT outcomes study.

275. This disclosure had no impact on Amarin's stock price or trading volume.

EE. The February 26, 2013 Press Release

276. On February 26, 2013, prior to the opening of the U.S. securities markets, Amarin issued a press release stating that it had submitted an sNDA to the FDA "seeking approval for the marketing and sale of Vascepa" for the ANCHOR indication.

277. The February 26, 2013 press release contained the following materially false and misleading statement attributed to defendant Zakrzewski: "Data from our pivotal Phase 3 placebo-controlled ANCHOR study showed that Vascepa is unique in that it significantly lowered both trigylcerides and LDL-cholesterol on top of optimized statin therapy and exhibited a safety and tolerability profile similar to placebo, unlike the clinical results of other trigylceride-lowering therapies." [Emphasis added.]

278. The February 26, 2013 press release further contained the following materially false and misleading statement attributed to defendant Zakrzewski: "If approved for the ANCHOR indication, Vascepa will be the only approved prescription omega 3 therapy for

cardiovascular health management in this patient population (TG ≥ 200 mg/dL and < 500 mg/dL with mixed dyslipidemia) and will represent the next generation of lipid management for potentially millions of patients." [Emphasis added.]

FF. The February 28, 2013 Press Release

279. On February 28, 2013, prior to the opening of the U.S. securities markets, Amarin reported Fourth Quarter and Year-End 2012 Financial Results. The February 28, 2013 press release reiterated Defendants' prior misrepresentations and material omissions. In the press release, Zakrzewski was quoted as saying, "In early 2013, we launched Vascepa for the MARINE indication and submitted a sNDA with the FDA seeking approval for the ANCHOR indication, which would enable promotion of Vascepa to a significantly larger patient population. [Emphasis added.]

280. Also in the release, the Company reported that "On February 26, 2013, Amarin announced that it submitted an sNDA to the FDA requesting approval to market and sell Vascepa to the patient population studied in the ANCHOR Phase III trial, adult patients with high triglyceride levels (≥200 mg/dL and < 500 mg/dL) who are also on statin therapy for elevated LDL-C, which we refer to as mixed dyslipidemia. All of the primary and secondary efficacy endpoints of the ANCHOR trial were achieved at the 4 gram dose." [Emphasis added.]

GG. The February 28, 2013 Conference Call

281. In conjunction with the earnings announcement, Amarin also conducted a conference call on February 28, 2013 at 4:30 p.m. EST, during which Defendant Zakrzewski spoke at length about ANCHOR:

> The indication study in the ANCHOR trial represents a significantly larger opportunity than the initial indication for MARINE launched last month as approximately 40 million Americans or one in five adults have triglyceride levels of at least 200 mg/dL. This group of patients represents a broader primary care

target market. In addition, as we submitted this, it was under a Special Protocol Assessment Agreement with the FDA as was our original MARINE indication.

The ANCHOR sNDA submission is based on the results of the ANCHOR clinical study in which as previously announced, we achieved all the primary and secondary end points including the reduction of LDL-C by a significant 6.2%. The safety information from the ANCHOR trial, which was similar to placebo, is already referenced in the existing approved label for Vascepa.

In accordance with our Special Protocol Assessment that I mentioned earlier, we announced the sNDA for ANCHOR two days ago, once the REDUCE-IT outcomes study was substantially underway. To remind everyone, this was the last requirement under the SPA that needed to be met prior to the approval of the ANCHOR indication, which we expect a PDUFA date by the end of 2013.

The end of year PDUFA date for the ANCHOR sNDA is anticipated assuming the FDA assigns a standard 10-month review cycle. If interested, the results of the ANCHOR trial were published and are available for viewing on the publications section of our corporate website. [Emphasis added.]

HH. The 2012 Form 10-K

282. In its Form 10-K for fiscal 2012, filed with the SEC on February 28, 2013, Amarin reiterated its prior misrepresentations and omissions with respect to the ANCHOR study. The Form 10-K stated (at 2) that:

Based on communications with the FDA, we believe that we are required to be "substantially underway" with a cardiovascular outcomes study at the time of the submission of our sNDA seeking approval of the ANCHOR indication. We believe that we achieved this requirement prior to submitting the sNDA. However, there can be no assurance that the FDA will agree with our assessment or that they will accept our sNDA for the ANCHOR indication. We do not believe the final results of the REDUCE-IT study will be required for FDA approval of Vascepa for the ANCHOR indication. [Emphasis added.]

283. The Form 10-K also added (at 13) that:

[I]n order to seek approval for a potentially expanded indication based on the ANCHOR study, we are required to have substantially enrolled subjects in our REDUCE-IT cardiovascular outcomes study at the time of our NDA submission for the ANCHOR indication. Based upon feedback from the FDA and in accordance with the SPA for the ANCHOR study, we do not believe that the results of the REDUCE-IT outcomes study are required for approval of the indication studied in the ANCHOR trial. [Emphasis added.]

284. Defendants Zakrzewski and Thero signed the 2012 Form 10-K, certifying, among other things, the truth of the Form 10-K.

II. The May 9, 2013 Press Release

285. On May 9, 2013, Amarin reported First Quarter 2013 Financial Results. In the press release, the Company announced that it "[r]eceived [FDA] acceptance for review of [sNDA] seeking approval for the marketing and sale of Vascepa for the ANCHOR indication (use as an adjunct to diet in the treatment of adult patients with high triglycerides (TG ≥200 mg/dL and < 500 mg/dL) with mixed dyslipidemia)."

286. Zakrzewski was also quoted highlighting "the acceptance for review by the FDA of our sNDA for the ANCHOR indication, which, if approved, would enable promotion of Vascepa to a significantly larger patient population." [Emphasis added.]

287. The press release further described Amarin's progress on the ANCHOR indication: "In a clinical trial of the use of Vascepa in the ANCHOR indication, as previously announced, Vascepa demonstrated statistically significant reductions in a broad spectrum of lipid and inflammatory markers, on top of optimized statin therapy, including significant reduction in LDL-C. In April 2013, as previously announced, the FDA accepted for review Amarin's sNDA for the ANCHOR indication that, upon approval, would enable Amarin to market and sell Vascepa for use in the ANCHOR indication. .... At a daily VASCEPA dose of 4 grams, all of the primary and secondary efficacy endpoints of the ANCHOR trial were achieved. As a result, Amarin is optimistic that the FDA will approve Vascepa for this indication." [Emphasis added.]

JJ. The May 9, 2013 Conference Call

288. Amarin also conducted a conference call at 4:30 p.m. EST in conjunction with its

First Quarter 2013 Earnings announcement. During that call, Defendant Zakrzewski spoke at length about the ANCHOR indication:

> As previously announced in the ANCHOR study, Vascepa demonstrated statistically significant reductions in a broad spectrum of lipid and inflammatory markers on top of optimized statin therapy, including significant reductions in LDL-C.…
>
> The ANCHOR indication upon approval, which is just seven short months from now, would enable Amarin to market and sell Vascepa for use as an adjunct to diet in the treatment of adult patients with high triglyceride that have mixed dyslipidemia, the patient population that has 200 mg/dL to 499 mg/dL trigs.
>
> * * *
>
> As a result of these things, Amarin's optimistic that the FDA will approve Vascepa for this indication.
>
> The current level of enrollment for REDUCE-IT has exceeded the requirement as outlined in our Special Protocol Assessment agreement with the FDA for the ANCHOR indication to have been accepted, which as you know happened last month. This is yet another reason why Amarin is optimistic that the FDA will approve Vascepa for the ANCHOR indication. [Emphasis added.]

289. During the Q&A session, in response to a question regarding insurance coverage and prior authorizations, Zakrzewski said, "[b]ut when we get to ANCHOR, if you think about it, right now, the pitch is we're approved for the same indication as our competition. When we get to ANCHOR, the answer is we're the only ones approved for this."

290. Zakrzewski concluded his remarks on the call by saying, with respect to JELIS, that:

> [A]t the end of the day for us it's about JELIS. That's the best comparator for our study, for our drug. And you know, JELIS is a study that in Japan saw a 19% reduction in mortality with our sister drug Epadel. And when they looked at patients at higher trig levels, they saw a 53% [reduction]. That's the one we should be thinking about, not supplements, not poorly designed old studies.

291. Following the call, Amarin shares opened at $6.95 on May 10, 2013, up from the May 9, 2013 close of $6.83.

KK. The June 19, 2013 Announcement of an Advisory Committee for the ANCHOR sNDA

292. On June 19, 2013, Amarin announced that "it was informed yesterday by the [FDA] that the FDA will convene an advisory committee on October 16, 2013 in connection with the FDA's review of the [sNDA] seeking approval for the use of Vascepa® (icosapent ethyl) capsules as an adjunct to diet in the treatment of adult patients with high triglycerides (TG ≥200 mg/dL and < 500 mg/dL) with mixed dyslipidemia."

293. This was a partial disclosure of the truth behind Amarin's false statements and indicated to investors the possibility that the FDA was unwilling to approve VASCEPA for the ANCHOR indication solely on the basis of the ANCHOR study.

294. Amarin shares declined 2.6% (from $6.47 to $6.30) on this news.

295. Rather than acknowledge the truth at this time, however, Defendants spun the news to suggest to investors the AdCom was expected and not negative for prospects for the ANCHOR indication of Vascepa.

296. The press release went on to quote Amarin consultant and the President of the American Board of Clinical Lipidology, Eliot Brinton, positively describing the AdCom:

> "For key first-in-class indications, an FDA advisory committee meeting is expected, and this public forum will be an important opportunity to discuss the ANCHOR data, which demonstrated VASCEPA's unique potential as an adjunct to diet in the treatment of adult patients with high triglycerides (TG 200-499 mg/dL) and mixed dyslipidemia," said Eliot A. Brinton, MD, FAHA, FNLA, Director of Atherometabolic Research, Utah Foundation for Biomedical Research, and President, American Board of Clinical Lipidology. "Currently, many of these patients are receiving another prescription omega-3 which is not indicated for this disorder. Having instead an omega-3 product which lowers LDL-cholesterol in addition to triglycerides, has tolerability comparable to placebo, and is FDA-approved for use on top of statin therapy would be a welcome addition to the physician's armamentarium for comprehensive lipid management. [Emphasis added.]

297. The press release further quoted Zakrzewski stating that "[w]ith the support of

the Amarin team, including our outside consultants, such as Christie [Ballantyne] and Eliot, we look forward to the advisory panel and working with the FDA to obtain regulatory approval of Vascepa for ANCHOR this year." Emphasis added.

LL. The July 8, 2013 Public Offering Announcement and Preliminary Prospectus Supplement

298. On July 8, 2013, Amarin announced that it was "offering to sell 21,700,000 American Depositary Shares ("ADSs") in an underwritten public offering. Amarin [ ] also granted the underwriters a 30-day option to purchase an additional 3,255,000 ADSs." Although Amarin shares had closed on July 8, 2013 at $6.17 per share, the press release reported that Amarin was selling the 21.7 million ADSs to the underwriters (Citigroup Global Markets Inc. and Jefferies LLC) at $5.60 per share, which resulted in net proceeds to Amarin of $121.52 million. The press release also stated that the underwriters had an overallotment option on 3,255,000 ADSs.

299. The press release stated that the underwriters would "offer the ADSs at prevailing market prices or otherwise from time to time through the Nasdaq Global Market, the over-the-counter market, negotiated transactions or otherwise."

300. At the time of this offering, Amarin had approximately 150.7 million ADSs outstanding. Thus, Amarin was increasing its capitalization by approximately 16.6% and sold the 21.7 million ADSs to the underwriters at prices significantly below the ADSs' historical prices. For example, from January 1, 2013 through July 8, 2013, Amarin ADSs traded at an average price of approximately $7.50 per share and a high of $9.16 per share on January 17, 2013. Even the low price during that period ($5.68 per share on June 27, 2013) was above the sale price to the underwriters.

301. Investors recognized that the size and price of the offering reflected Amarin's

greater concern – than previously expressed -- that the FDA would require Amarin to complete the REDUCE-IT trial prior to approving Vascepa for the ANCHOR indication.

302. Amarin shares closed on July 9, 2013 at $5.58 per share on volume of approximately 11.9 million shares, and closed on July 12, 2013, at $5.265 per share – as the underwriters apparently struggled to sell off the 21.7 million ADSs acquired on the secondary offering. Reported volume on July 8, 2013 was approximately 2.2 million shares.

MM. The July 10, 2013 Prospectus Supplement

303. Amarin filed a Prospectus under Rule 424(b)(5) with the SEC on July 10, 2013 for the offering of 21.7 million ADSs at $5.60. Among other things, the Prospectus stated:

> In December 2011 we announced commencement of patient dosing in our cardiovascular outcomes study of Vascepa, titled REDUCE-IT (Reduction of Cardiovascular Events with EPA – Intervention Trial), which is designed to evaluate the efficacy of Vascepa in reducing major cardiovascular events population on statin therapy. We do not believe the final results of the REDUCE-IT study will be required for FDA approval of Vascepa for the ANCHOR indication, although there can be no assurance that this will be the case. [Emphasis added.]

304. The added terminology that "although there can be no assurances that this will be the case," was not contained in any of Defendants' prior statements, including the January 6, 2011 Prospectus Supplement. That additional terminology itself is a belated acknowledgment, that the final results of the REDUCE-IT study were likely to be required by the FDA for approval of Vascepa for the ANCHOR indication.

305. Although Defendants belatedly qualified their optimism in the Prospectus Supplement, they still failed to disclose the FDA's stated concern with respect to the efficacy of the ANCHOR data.

306. Defendant Zakrzewski and the other Individual Defendants knew of the falsity of

these statements and allowed them to be disseminated. Zakrzewski signed the Underwriting Agreement on the 2013 offering, which was part of an 8-K filed with the SEC on July 10, 2013.

NN. The July 12, 2013 Press Release

307. On July 12, 2013, Amarin announced that it had completed its previously announced underwritten public offering of 21,700,000 ADSs, at $5.60 per ADS, resulting in net proceeds to Amarin of approximately $121.1 million.

OO. The August 8, 2013 Press Release and Conference Call

308. On August 8, 2013, Amarin announced financial results for the second quarter ended June 30, 2013. A press release issued by Amarin in connection with the quarterly report stated in relevant part:

> The ANCHOR study, which evaluated the efficacy of VascepA in lowering triglycerides on top of optimized statin therapy for adult mixed dyslipidemia patients with high triglyceride levels (≥200 to < 500 mg/dL), was conducted under a special protocol assessment, or SPA, agreement with the FDA. An SPA is generally considered to be binding upon the FDA except in limited circumstances, such as if the FDA identifies a ntific issue essential to its determining the efficacy or safety of a drug. Amarin has not been informed by FDA of any such essential issue. Amarin believes that it achieved all of the requirements of the SPA agreement. In particular, in the ANCHOR trial, with Vascepa 4 grams per day, all primary and secondary efficacy endpoints were achieved, including a reduction in LDL-C levels compared to placebo. Amarin is optimistic that the FDA will approve Vascepa for this indication and looks forward to the advisory committee meeting as an opportunity to highlight the positive safety and efficacy profile of Vascepa.
>
> * * *
>
> Consistent with Amarin's Special Protocol Assessment (SPA) agreement, and based on the company's discussions with the FDA, the company does not believe the final results of the REDUCE-IT study will be required for FDA approval of Vascepa for the ANCHOR indication, although there can be no assurance that this will be the case. [Emphasis added.]

309. The August 8, 2013 press release quoted defendant Zakrzewski as making the following additional materially false and misleading statement: "[W]e believe we are well

positioned … to expand Vascepa labeling from our approved MARINE indication to the significantly larger population represented by our proposed ANCHOR indication." [Emphasis added.]

310. In connection with the earnings release, Amarin hosted a conference call to discuss the second quarter earnings. During his prepared remarks, Defendant Steven B. Ketchum, Amarin's head of R&D sought to downplay any risk to the approval of Vascepa for the ANCHOR indication based on the outcomes of recent studies:

> We will be well prepared for the Advisory Committee meeting and we remain confident regarding the approval of Vascepa for the ANCHOR indication.
>
> * * *
>
> Approximately 40 million adult Americans, or one in five, have triglyceride levels of at least 200 milligrams per deciliter. Given the first of a kind approval being sought and the size and scope of this population, it is understandable why the FDA would recommend an AdCom meeting.
>
> Having an AdCom meeting is also consistent with trends that have influenced the FDA to seek greater input and allow greater visibility into its regulatory decision making. Our preparations include obtaining feedback and guidance from leading clinicians in the field and we have already conducted outcomes in an effort to prepare to answer a broad range of questions that could be asked during this meeting.
>
> As is typical, the FDA has not yet informed us of the members of AdCom panel or the questions that they will ask. This has not hindered our ability to prepare. We and our advisors believe that we have appropriate and acceptable responses to a wide range of potential questions. These responses are aided by the favorable efficacy and safety profile of the Vascepa.
>
> As a reminder, the ANCHOR study was conducted under Special Protocol Agreement with the FDA. This is an extra step that we took with the FDA before commencing the ANCHOR study to ensure that we had a written understanding with the FDA as to what they required for approval of the ANCHOR indication. We believe that we have achieved all that is required. More specifically, we achieved all of the primary and secondary clinical endpoints of the study.

* * *

We had various discussions with the FDA, leading up to our submission of the sNDA for the ANCHOR indication. Most of these discussions focus on whether or not we were substantially underway with the REDUCE-IT cardiovascular outcomes study.

* * *

For clarity, the SPA and corresponding regulatory discussions in no way require us to have the outcomes study completed for the sNDA to be accepted for review or for the ANCHOR indication to be approved.

* * *

Some investors have interpreted the AdCom as implying that the agency intends to change the rules for Amarin with respect to the status of the REDUCE-IT outcomes study. We have not seen evidence of such a change. We had considerable discussion with the agency over what constituted substantial underway for the outcomes study and during these discussions, never did they suggest changing their requirements.

* * *

While we believe we do not need the REDUCE-IT study to be completed for approval of the ANCHOR indication, we do believe that this study is positioned for success. Highly pure EPA in the JELIS study, albeit in a Japanese population demonstrated significant reduction in cardiovascular events over statin therapy alone.

Some investors have argued that because the AIM-HIGH study with Niacin failed, that the FDA will change its view on Vascepa. As a reminder, Niacin is an HPO raising drug not a triglyceride lowering drug and Niacin remains approved on the market. Some also argue the Fenofibrate failed the outcomes studies and this will have a bearing on getting the FDA to reassess its requirement for Vascepa. Fenofibrate were not directly studied in a patient population with alleviated triglycerides in an outcomes setting. In fact, in the ACCORD study of fenofibrates, the subgroup of patients who had alleviated baseline triglycerides showed improved outcomes.

This has not been widely publicized because this was not the pre-specified primary endpoint of the study and the study was not powered for this purpose, but it is supportive of the value of lowering triglyceride levels in patients with high triglycerides. In addition, Vascepa not only lowers triglycerides but lowers distraction of other lipid parameters including, compared to placebo, LDL-C, a

> well established marker of outcomes and Vascepa also lowered various other inflammatory biomarkers. Vascepa does this with a safety profile which is comparable to placebo.
>
> Today, patients with alleviated triglycerides are being treated on-label or off-label with a variety of drugs which increase LDL or have various other side effects. We find it difficult to believe that given this environment and the safety and efficacy profile of Vascepa, that Vascepa won't be approved for this expanded indication.
>
> * * *
>
> It is unfortunate that the authors of that med analysis did not identify that the one study which was successful with the JELIS study of our sister drug Epadel in which highly pure EPA was affected in improving cardiac outcomes on top of statin therapy in Japanese patient population. [Emphasis added.]
>
> Overall, we have seen nothing presented anywhere that has diminished our overall confidence in the clinical opportunity provided by Vascepa. Our advisors and thought leaders agree, and urge that we be focused on more relevant topics such as reduced LDL particle concentration from Vascepa, the anti-inflammatory response of Vascepa and incremental efficacy of vascepa on top of increased potency of statin therapy. [Emphasis added.]

IX. THE TRUE FACTS ARE REVEALED IN THE FDA'S BRIEFING DOCUMENT AND THE ADVISORY COMMITTEE MEETING

311. The true facts were partially revealed in a series of disclosures from October 11, 2013 through October 29, 2013.

312. On October 11, 2013, the FDA published its Briefing Document for the October 16, 2013 Advisory Committee Meeting. That Briefing Document both summarized the FDA's concern expressed to Amarin in July 2008 that there was a lack of substantial scientific evidence that the reduction of TGs on patients with a baseline treatment of statins alone evidenced reduced risk of cardiac issues and stated that based on published test results first available to Amarin in 2010 that there was a continuing lack of proof that a reduction in TGs alone would diminish the incidence of cardiac events:

> During a pre-IND meeting with the applicant in July 2008 … the Division noted

> that there was a lack of prospective, controlled clinical trial data demonstrating that pharmaceutical reduction of non-HDL-C (or TG) with a second drug, in patients with elevated TG Levels at LDL goal on statin therapy, significantly reduces residual cardiovascular risk. The Division referenced trials ongoing at the time (e.g., AIM-HIGH, ACCORD-Lipid) that, while not able to assess the effect of specifically lowering non-HDL-C (or TG) on clinical outcomes, would be expected to provide important information on the incremental benefit of adding a second lipid-active drug to statin therapy. It was stated that before an indication would be entertained for Ethyl-EPA as add-on to statin therapy in patients with elevated TG levels, the applicant at a minimum would have to provide results from a 12-week study with lipid endpoints as well as initiate an appropriately designed cardiovascular outcomes study. [Emphasis added.]
>
> * * *
>
> Several cardiovascular outcomes trials of non-statin lipid-modulating therapy, such as those referenced by the Division in 2008, have since completed. ACCORD-Lipid, AIM-HIGH, and HPS2-THRIVE, which were designed to target residual cardiovascular risk by improving lipid parameters other than LDL-C (e.g., HDL-C and/or TG) in patients optimally treated with statin therapy, failed to demonstrate unequivocally additional cardiovascular benefit from non-statin lipid-modulating drugs. Several hypotheses could be put forward regarding the failures of these large, carefully designed trials to demonstrate benefit on their primary endpoints, but the evidence to date certainly challenges the hypothesis that adding lipid-modulating therapies to patients optimally treated with statins will reduce residual cardiovascular risk. [At 9; emphasis added.]

313. Amarin's stock price fell $1.38 per share on October 11, 2013 (from $6.37 to $5.09) as a result of the revelations of true facts in the FDA's Briefing Document. Trading volume was an extraordinarily high 37.9 million shares.

314. Subsequent to the scheduling of the AdCom, certain analysts raised concerns that ACCORD and AIM-HIGH might cause the FDA to reconsider approving ANCHOR based only on surrogate endpoints (as had been Amarin's consistent representations of the FDA's position). Thus, for example, a Canaccord Genuity analyst (Ritu Baral) wrote in a research report dated June 19, 2013 that the "FDA may ask for expert opinion on recent CV outcomes trials of drugs that cause TG lowering but did not generate data showing lower rates of cardiac events (e.g. STRIDE, AIM-HIGH, ACCORD, FIELD)."

315. However, Ms. Baral maintained her buy rating and $17.00 price target in reliance on defendants' misrepresentations that "they have met every condition of the ANCHOR SPA."

316. On October 16, 2013, the NASDQ halted trading in Amarin ADSs while the Advisory Committee considered Amarin's NDA based on the ANCHOR study. Those deliberations were conducted in a public forum. The FDA presenter emphasized at the Advisory Committee Meeting that Amarin was advised by the FDA in July 2008, with respect to the application for approval of the ANCHOR indication based only on the ANCHOR study, that "ongoing cardiovascular outcomes trials – e.g., ACCORD-Lipid and AIM-HIGH – would provide *important* information on the incremental benefit of adding a second lipid-altering drug to statin therapy." [Emphasis added.]

317. Christie Ballantyne was the principal investigator for Amarin on the ANCHOR study and was expected to present the ANCHOR study at the AdCom. Ballantyne previously had been a principal Amarin spokesperson in press releases with respect to the ANCHOR study. According to Confidential Witness A, who was told by the Medical Science Liaisons, Ballantyne "was not comfortable speaking on Amarin's behalf" at the AdCom and thus was not present.

318. Confidential Witness B was a Senior Medical Science Liaison for Amarin based in a mid-Atlantic state. Confidential Witness B was employed by Amarin from July 2012 to October 2013. Confidential Witness B reported to Sephy Philip, Senior Director of Medical Affairs, and to Christina Copeland, Medical Director. Dr. Philip was one of the presenters on behalf of Amarin at the October 16, 2013 AdCom.

319. As a Medical Science Liaison (MSL), Confidential Witness B conducted educational and outreach efforts to raise awareness about Vascepa in the medical community by

giving presentations and answering questions at the Vascepa booth at medical conventions. He also approached key opinion leaders in the cardiovascular and lipid medical communities to discuss Vascepa and solicit their opinions about the drug.

320. He participated in weekly MSL team conference calls, and occasionally went to the company's headquarters in New Jersey for MSL team meetings.

321. When Amarin was preparing for the October 2013 AdCom, Confidential Witness B attended one session at Amarin headquarters in what he recalled was September 2013.

322. As a Senior Medical Science Liaison, Confidential Witness B was responsible for interacting with the medical and academic community with respect to Vascepa.[6]

323. When Confidential Witness B attended the prep session for the FDA meeting, he was under the impression that Dr. Christie Ballantyne, the principal investigator on the ANCHOR study, would be presenting the results of the study and speaking on behalf of Amarin at the FDA meeting.

324. "He was going to be the main presenter," Confidential Witness B said of Ballantyne. "He was going to walk them through the clinical data."

325. A week before the FDA meeting, however, Confidential Witness B learned that Ballantyne had declined to participate and was not going to present the data or speak on behalf of Amarin.

326. Ballantyne's decision surprised Confidential Witness B because principal investigators usually are willing to present their data and speak on behalf of the company at FDA meetings.

327. "I found that odd," Confidential Witness B said. "I'm sure it's happened before

[6] Lead Plaintiff has confirmed Confidential Witness B's job description and employment with Amarin on LinkedIn.

but not in my 20 years in the industry. It clearly raised a red flag for me."

328. At the October 16, 2013 Advisory Committee Hearing, Dr. Eric Colman, the Deputy Director for the Division of Metabolism and Endocrinology Products (DMEP) of the Center for Drug Evaluation and Research of the Food and Drug Administration, reiterated that the FDA had not committed in 2008 to approve Vascepa based on the ANCHOR trial but rather to evaluate Vascepa in light of the science available in the future, including the results of the ongoing ACCORD, AIM-HIGH and THRIVE tests (at 21):

> [T]he division noted to the company that there were no controlled clinical trial data, demonstrating that the reduction of triglyceride levels with a second drug in patients with high TG at LDL goal on a statin therapy significantly reduces the residual risk for cardiovascular disease.[7] Moreover, we discussed and we noted that there were ongoing cardiovascular outcomes trials – ACCORD-Lipid, and AIM-HIGH, to name two – that these trials would provide important information on the incremental benefit of adding second lipid-altering drug to statin therapy.

329. Specifically, Colman stated at the AdCom as follows (at 258):

> So back in 2007/2008, we weren't in a position to say there's no way you're going to get this approved without doing a cardiovascular outcomes trial and completing it and then coming back to see us. We knew these other trials were ongoing, ACCORD, AIM-HIGH, THRIVE. While not the same compound, we knew that they would add some information. So we felt it was very reasonable to say, look, do a lipid endpoint study for 12 weeks so we get to see what the lipid profile looks like. But we want you to at least have the cardiovascular outcomes trial up and running with 50 percent enrollment so that we know that even if we approve it now, it'll get done fairly quickly. And if the folks feel that it shouldn't be approved at this point, the trial's up and running and we still will get that data fairly shortly. I also think that if ACCORD Lipid and AIM HIGH and THRIVE were positive, I think we would have a different discussion today.

---

[7] This fact was acknowledged at the AdCom (at 31, 42, 43) by Dr. Michael Miller, an expert in hypertriglyceridemia and hyperlipidemia, who testified at the AdCom on behalf of Amarin ("there is some controversy over whether or not reductions in triglycerides will lead to a reduction in cardiovascular risk."; "no outcomes studies to date have specifically addressed patients with triglycerides above 200 milligrams per dL"; "[t]hese recent studies did not demonstrate a reduction in CV events").

330. Dr. Colman stated further (at 260):

> And we weren't in a position back in 2008 to feel like we had the proper support and data to say to Amarin, there's no way you will ever get this indication unless you complete an outcomes trial. We thought there was enough uncertainty to give them the advice we did. And as it turns out, we've had additional studies that have been completed that I think do play into today's discussion.

331. Mary Roberts, a Clinical Reviewer with the FDA, further testified at the Advisory Committee meeting (at 131-32) that Amarin was informed specifically at the July 2008 meeting, as reflected in formal minutes of that meeting, that FDA approval of Vascepa for the ANCHOR indication was dependent on the success of the ACCORD-Lipid and AIM-HIGH trials:

> Discussions between the division and the sponsor regarding the development of Vascepa for dyslipidemia began in 2008….
>
> In regards to the population with persistently high triglycerides on statin therapy, the minutes from this meeting reflect the division's uncertainty, which was conveyed to the sponsor regarding whether pharmacological reduction of non-HDL or triglycerides would translate into additional cardiovascular benefit among patients already treated with statins.
>
> Specifically, the sponsor was told the AIM-HIGH, ACCORD, and PROVE-IT studies will provide important information on the incremental benefit of adding a second lipid active drug to statin therapy. Furthermore, the division stated, "Before accepting an application for a treatment indication in this population, at a cardiovascular outcomes trial needs to be well underway at the time of review of the 12-week lipid endpoint study." [Emphasis added.]

332. Roberts reviewed ACCORD-Lipid, AIM-HIGH and HPS2-THRIVE, and concluded at the Advisory Committee hearing (at 147), that "to date there is no conclusive evidence that additional modifications of non-LDL lipid and lipoproteins translate into further cardiovascular benefit in the setting of optimized statin therapy and LDL control in the overall population studied." *See also* Advisory Committee Tr. at 157: "Recent cardiovascular outcomes trials with fenofibrate [ACCORD-Lipid] and niacin [AIM-HIGH] call into question

whether targeting lipids and lipoproteins other than LDL yield incremental cardiovascular benefit in the setting of contemporary statin therapy…. Cardiovascular outcomes trials with Omega-3 fatty acids do not consistently support benefit. Thus, whether the lipid changes, specifically triglyceride and non-HDL, observed in the ANCHOR study will translate into lower rates of major adverse cardiovascular events is debatable."

333. Roberts also concluded (at 154-56) that the JELIS study was not indication of efficacy in the ANCHOR patient population, among other things, because (i) "the patient population was exclusively Japanese," (ii) "the majority of the participants were women," (iii) "at baseline, patients had a much higher LDL," (iv) "a low dose of statins was used. It is unknown if these patients had been optimally treated with statins using contemporary LDL targets in the United States," (v) "JELIS was an open label trial, which could influence patient and physician behavior in reporting of symptoms, decisions regarding hospitalization, and referral of events for adjudication," (vi) "unstable angina was a primary contributor of the overall positive result and is considered a softer endpoint than fatal cardiovascular events," (vii) the JELIS study had not "been submitted to the division for independent review," and (viii) "[t]here was only a 5 percentage point difference in triglycerides between the two groups."

334. Dr. Brendan Everett, an Assistant Professor at the Harvard Medical School and Director of General Cardiology Inpatient Service Cardiovascular and Preventive Medicine at the Brigham and Women's Hospital in Boston, Massachusetts, and a member of the Advisory Committee, similarly commented at the Advisory Committee hearing that the sponsor's reliance on JELIS was "shaky" (at 184-85).

335. Dr. Ellen Seely, Professor of Medicine, Harvard Medical School, Division of Endocrinology, Diabetes and Hypertension, Brigham and Women's Hospital, Boston, MA, and

a member of the Advisory Committee, commented with respect to JELIS (at 253): "it was an open label study. The cutoffs for entry of the lipid levels were very different than what we're looking at for the indication."

336. Dr. Wilson, a member of the Advisory Committee also commented with respect to add-on therapy, generally (at 173), "[d]o you reach for escalating the statin dose and getting maybe another 6 percent, or do you reach for a different class of molecule?"

337. The FDA's Advisory Committee testimony also disclosed other troubling facts, including that there was a concern that the mineral oil administered as a placebo may not have been inert and may have acted to inhibit absorption of the statin, thus distorting the ANCHOR test results.

338. Mary Roberts testified (at 138-41) that the FDA had discussed its concern that mineral oil was not inert with Amarin: "with the exception of HDL, the changes observed [in lipid and lipoprotein endpoints] within the placebo group went in an adverse direction from baseline to week 12…. In the case of ANCHOR … the changes observed within the placebo group stood out as atypical for similarly designed lipid-lowering trials that we have reviewed, which gave us pause, especially since the changes went in an unfavorable direction.… For REDUCE-IT, our primary concern was whether or not there was a possibility that the mineral oil could attenuate the effect of a statin, perhaps by inhibiting absorption. Because we do not have any hard evidence for an interaction, such as a formal drug-drug interaction study, we discussed our concerns with the sponsor and asked that they task the REDUCE-IT data monitoring committee with evaluating the accruing lipid data with this concern in mind." [Emphasis added.]

339. Dr. Peter Wilson, a Professor of Medicine at the Emory University School of

Medicine, and a member of the Advisory Committee, emphasized his consternation with the use of mineral oil as placebo (at 172):

> [G]osh, I wish we didn't have the placebo here…. [Y]ou need a better placebo for Omega-3 trials, maybe a micro-fraction of Omega-3 and some non-absorbable carbohydrates so that they have the taste of Omega-3, because these placebos confused me more than the drugs.

340. William R. Hiatt, Professor of Medicine, Division of Cardiology, University of Colorado School of Medicine, and a member of the Advisory Committee, commented (at 273): "the changes from baseline are pretty dramatic on triglyceride as the primary, so I don't think the drug is inert. It's biologically active. It's changing the primary endpoint significantly."

341. The Advisory Committee, after hearing testimony and deliberating on Amarin's application, voted 9-2 to recommend that the FDA reject the sNDA for ANCHOR, adopting the FDA's position that the ANCHOR study itself was not indicative of the efficacy of the drug to reduce severe cardiovascular events, and that the FDA should wait for completion of the REDUCE-IT study before approving Vascepa for the ANCHOR indication.

342. Defendant Ketchum acknowledged at the Advisory Committee meeting (at 269) that Amarin, by virtue of "a lot of collaboration with the FDA," was "aware of some of the limitations of ACCORD, AIM-HIGH and HPS2-THRIVE."

343. Further, Defendant Ketchum, in his testimony before the AdCom, registered his concurrence (at 70) that the long-term REDUCE-IT outcomes "confirmatory study" was "necessary."

344. Upon the resumption of trading on October 17, 2013, Amarin ADSs declined by an additional $3.16 per share (from $5.17 per share to $2.01 per share), on extraordinary trading volume of 105.7 million shares.

345. On October 29, 2013, Amarin filed a Form 8-K with the FDA. The Form 8-K

informed investors that the FDA had "rescinded the ANCHOR study special protocol assessment agreement." According to the Form 8-K, "the FDA cited results from the ACCORD-Lipid and AIM-HIGH outcomes trials, as well as the publicly presented results from the HPS2-THRIVE outcomes trial, which the FDA stated in its October 29, 2013 notice to Amarin, fail to support the hypothesis that a triglyceride-lowering drug significantly reduces the risk for cardiovascular events among statin-treated patients with mixed dyslipidemia and residually high serum triglyceride levels (200-499 mg/dL)."

346. This news caused an even further decline in Amarin's price, from $2.10 to $1.81 on high volume of 17.16 million.

347. The grounds for the Advisory Committee vote and suspension of the SPA are precisely the same grounds Amarin was apprised of by the FDA at the pre-NDA meeting in July 2008 (quoted *supra* at Paragraph 28), that would require the completion of the REDUCE-IT outcomes study prior to approval of the ANCHOR indication.

348. None of the Individual Defendants denied at the AdCom or otherwise being aware during their employment at Amarin that Amarin was told by the FDA in July 2008 that approval of Vascepa for the ANCHOR indication based only on the ANCHOR Phase III trial depended on the success of the ACCORD-Lipid and AIM-HIGH studies.

349. Commentators considered the October 11, 16 and 29, 2013 revelations with respect to the FDA's position on ACCORD-Lipid, AIM-HIGH, HPS2-THRIVE and REDUCE-IT to be new information previously unknown to the market and that if known would have been material to investors' investment decisions regarding Amarin.

350. For example, a Jefferies Company Note published on October 17, 2013, stated, in part, "[w]e were surprised by the strong FDA bias for delaying approval for CV outcomes

data."

351. Further, an October 17, 2013 JPMorgan research report downgraded AMRN stating, "[g]iven the negative panel vote, we do not expect an approval on the December 20 PDUFA date and see this outcome as a significant set-back for Vascepa's commercial outlook."

X. SCIENTER

352. As alleged herein, Defendants acted with scienter in that they knew, or recklessly disregarded, that the public documents and statements issued or disseminated in the name of the Company or in their own name were materially false and misleading; knew or recklessly disregarded that such statements or documents would be issued or disseminated to the investing public; and knowingly and substantially participated or acquiesced in the issuance or dissemination of such statements or documents as primary violators of the federal securities laws. The additional allegations below strongly support a strong inference that Amarin and the Individual Defendants acted with scienter.

353. By virtue of Amarin's July 14, 2008 meeting and March 14, 2011 conference call with the FDA as well as the July 6, 2009 and August 5, 2011 SPAs, among other things, Defendants had actual knowledge that the FDA was substantially less likely to approve Vascepa for the ANCHOR indication in the absence of completion of the REDUCE-IT study, and further, that the FDA would look to the AIM-HIGH and ACCORD-Lipid studies as indicative of whether the reduction in TGs (without an outcomes study) had been scientifically proven to diminish the incidence of severe cardiovascular events. Moreover, Defendants had actual knowledge of FDA and internal concern that mineral oil was not inert (¶¶ 99-101, 104-06, 408-10) and that JELIS was not representative of the REDUCE-IT study. *See*, *e.g.*, ¶¶ 22, 180.

A. Vascepa Is Amarin's "Core" Business

354. That VASCEPA is both Amarin's core business and critically important to the Company supports a strong inference of scienter. When a senior officer of a company makes a public statement regarding core operations of the company, and that statement turns out to be false, this supports a strong inference that the officer knew the statement was false when made. VASCEPA and its approval for the ANCHOR indication are tremendously important to Amarin. As Amarin acknowledged in its public filings, at all material times, the Company relied on Vascepa as its primary product and the market for the ANCHOR indication is purportedly approximately ten times larger than the market for the MARINE indication. Amarin's future profitability is dependent on obtaining FDA approval to market Vascepa for the ANCHOR indication.

355. Additionally, the Company is relatively small in size and considered itself a "small, yet highly focused team,"[8] working on its product, Vascepa.

356. Given the critical importance of Vascepa and its approval for the ANCHOR indication to Amarin, it is simply not plausible that Amarin's most senior management, including those directly responsible for overseeing, managing and reporting on its financial state, were not privy to the internally known adverse facts disclosed to the Company by the FDA in July 2008. In fact, defendant Ketchum acknowledged at the AdCom and in subsequent correspondence to the FDA that Amarin was aware throughout the Class Period of the FDA's "substantial uncertainties" concerning surrogate endpoints, which could only be addressed by completing the REDUCE-IT study. *See*, *e.g.*, ¶¶ 28, 130, 142, 413-14.

357. Individual Defendants named herein were the officers primarily responsible for speaking on behalf of Amarin to the investing public (and in certain instances also signatories of

[8] As stated by Defendant Zakrzewski during the July 26, 2012 Investor Conference Call.

the Company's public filings during the Class Period). The Individual Defendants had ultimate control over Amarin's public statements, and personally made numerous materially false and misleading statements concerning Vascepa during the Class Period. Each of the Individual Defendants, as well as Declan Doogan and Paresh Soni, held key positions and responsibilities within the Company such that they would have been knowledgeable about Amarin's core business.

358. As CEO, Zakrzewski was ultimately responsible for, and exercised control over, the Company.

359. As was the case with Zakrzewski, the Chief Executive Officer is typically the highest-ranking member of the executive team and is responsible for managing the company's operations and resources. Defendant Zakrzewski was CEO and Chairman of Amarin from January 2010 through the end of 2013 and can be presumed to be knowledgeable concerning its core business practices. He was the officer primarily responsible for speaking on behalf of Amarin to the investing public from the time he joined the Company, and did in fact make many statements to the investing public during the Class Period as evidenced by the multiple false and misleading statements cited herein. This included certifying pursuant to the Sarbanes-Oxley Act that the information in Amarin Form 10-K reports for years ended 2010, 2011 and 2012 "fairly presents, in all material respects, the financial condition and result of operations of the Company."

360. Zakrzewski was appointed Executive Chairman of Amarin effective January 1, 2010. In a press release dated December 2, 2009, Zakrzewski was quoted as saying that he had reviewed "Amarin's compelling business plan and cardiovascular development strategy," which certainly would have included the July 14, 2008 Minutes and August 6, 2009 SPA.

361. From the time he was appointed CEO in 2010, the Company touted his industry experience and expertise. The press release announcing his appointment stated, in part, "Mr. Zakrzewski has more than 20 years of industry experience, including significant contributions to Reliant Pharmaceuticals as Chief Operating Officer during the period when Omacor®/LOVAZA® was successfully developed, launched, and marketed for reducing very high triglyceride levels, … leading to its 2007 acquisition by GlaxoSmithKline."

362. The press release stated that Zakrzewski was replacing Colin Stewart, who had been serving as Amarin's President and CEO and a director, and had resigned effective November 10, 2010 "to address personal matters." Stewart had been appointed Amarin's Chief Executive Officer effective August 16, 2010, and served in that capacity for less than three months.

363. Clear evidence of Zakrzewski's willingness to commit fraud was that even though the 2008 Minutes and 2009 SPA clearly required that REDUCE-IT be at least 50% enrolled before the FDA accepted the ANCHOR sNDA for filing, Zakrzewski dissembled the truth and told investors that Amarin was negotiating with the FDA to require that REDUCE-IT be only 25% enrolled prior to submitting the sNDA. *See* ¶ 262.

364. Defendant Thero was the Company's President and Chief Financial Officer from November 5, 2009 through December 2013. On January 1, 2014, he replaced Zakrzewski as CEO.

365. In the Amarin press release announcing his appointment on November 6, 2009, the Company stated, "[i]n this role, Mr. Thero will have broad responsibility for financial and administrative matters of the Company and be actively involved in corporate development and other strategic and operational matters.

366. The press release further stated that "Mr. Thero has more than 20 years of senior financial and operational management experience including over 15 years supporting the growth of life science companies.

367. According to the employment agreement between Amarin and Thero, he was responsible for and had control over "such duties and responsibilities as are customarily performed by the chief financial officer of a company of the size and nature of [Amarin]", including public reporting and compliance with applicable policies, regulations and laws:

368. As Amarin's CFO, Defendant Thero had control over the reporting of Amarin's financial activities and was primarily responsible for speaking on behalf of Amarin to the investing public providing information on matters relating to Amarin's financial status, and in fact did make statements during the Class Period to the public concerning ANCHOR and the FDA as evidenced herein. This included certifying pursuant to the Sarbanes-Oxley Act that the financial information in Amarin Form 10-K reports for years ended 2010, 2011 and 2012 "fairly presents, in all material respects, the financial condition and result of operations of the Company." Thero directly reported to Zakrzewski and shared control over Amarin's business and public statements.

369. Further, Thero signed all of the Form 8-K filings attaching the press releases containing false statements as alleged herein. Defendant Thero was identified as the "Investor Contact" on the press releases dated December 16, 2010 and January 5, 2011, containing material misrepresentations.

370. Defendant Ketchum has been the Company's Senior Vice President and President of Research and Development since February 2012. According to the employment agreement between Amarin and Ketchum dated February 12, 2012, he was an executive officer

of the Company responsible for Amarin's research and development efforts. As the Company's Senior Vice President and President of Research and Development, he spoke on behalf of Amarin to the investing public providing information on matters relating to research and development, including Amarin's progress in the development and testing of Vascepa as evidenced herein, and was the principal liaison with the FDA.

B. Financial Motives of Individual Defendants Support a Strong Inference of Scienter

371. Defendant Zakrzewski was financially motivated to commit the fraud and artificially inflate the market price of Amarin stock. While in possession of material, nonpublic information regarding the prospects for approval of Vascepa for the ANCHOR indication, he sold substantial Amarin ADSs at artificially inflated prices, reaping huge profits.

372. As part of Zakrzewski's remuneration, he was granted options on December 21, 2009 to purchase 1,170,000 ordinary shares under the Amarin 2002 Stock Option Plan at an exercise price of $1.35 per share (the options were to vest in four equal installments over four years). On November 11, 2010, Zakrzewski was granted options to purchase an additional 1,750,000 shares under the same Plan at an exercise price of $3.40 per share (also to vest over four years in equal installments). During 2011, 730,000 of his shares became exercisable and he sold 460,000, or 63% of his total shares available to sell. During 2012, another 730,000 of his shares became exercisable and he sold 610,000, or 84% of his total shares available to sell.

373. In sum, from February 22, 2011 through October 1, 2012, Zakrzewski sold 1,070,000 Amarin ADSs for total net proceeds of $11,898,553.

Joseph Zakrzewski, CEO

Sale Date	Shares Sold	Sale Price	Exercise Price	Option Expiration Date	Gross Proceeds	Net Proceeds
2/22/2011	100,000	$8.54	$1.35	12/21/2019	$854,000	$719,000
2/25/2011	50,000	$8.16	$1.35	12/21/2019	$408,155	$340,655
2/25/2011	10,000	$8.16	$1.35	12/21/2019	$81,631	$68,131
4/18/2011	200,000	$15.76	$3.40	12/21/2019	$3,152,000	$2,472,000
4/18/2011	100,000	$15.76	$1.35	11/11/2020	$1,576,000	$1,441,000
FY 2011	**460,000**				**$6,071,786**	**$5,040,786**
3/23/2012	160,000	$11.59	$1.35	12/21/2019	$1,854,560	$1,638,560
5/29/2012	150,000	$11.97	$1.35	12/21/2019	$1,795,200	$1,592,700
7/27/2012	71,946	$14.58	$1.35	12/21/2019	$1,048,973	$951,846
7/27/2012	78,054	$14.07	$1.35	12/21/2019	$1,098,220	$992,847
10/1/2012	150,000	$12.56	$1.35	12/21/2019	$1,884,315	$1,681,815
FY 2012	**610,000**				**$7,681,267**	**$6,857,767**
TOTALS	**1,070,000**				**$13,753,053**	**$11,898,553**

374. Plaintiff's charts of insider selling are based on a tabulation of Form 4 filings. Amarin's 2014 Proxy Statement (at 37) however states that as of December 13, 2013. Zakrzewski only had 35,000 of the options issued in 2009 outstanding (rather than the 300,000 options as plaintiff had calculated):

Grant Date	Shares Granted		Exercise Price	Option Expiration Date	Shares held in 2014	Shares Sold		Net Proceeds
12/21/2009	1,170,000	(1)	$1.35	12/21/2019	35,000	1,135,000	(3)	$9,426,452
11/11/2010	1,750,000	(2)	$3.40	11/11/2020	1,550,000	200,000		$2,472,140

(1) As per F-1 filed 12/14/09.
(2) As per 10-K filed 3/16/11.
(3) This figure is based on the difference between the shares granted column and the shares sold column (which came from the Proxies filed on 5/2/11 and 4/30/14). However, the total shares sold based on Form 4 filings indicate only 870,00 shares have been sold.

Thus, Zakrzewski likely has an additional 265,000 shares of insider sales and additional insider profits not accounted for in the Form 4 filings.

375. That Zakrzewski did not exercise options or sell shares after October 1, 2012 should come as no surprise since he had already exercised and sold substantially all the vested stock options that had been granted in 2009 and 200,000 of the options granted in 2010.

376. Defendant Thero was also financially motivated to commit the fraud and artificially inflate the market price of Amarin stock. While in possession of material, nonpublic information regarding the prospects for approval of Vascepa for the ANCHOR indication, he sold substantial Amarin ADSs at artificially inflated prices, reaping huge profits.

377. As part of Thero's remuneration, he was granted an option on December 21, 2009 to purchase 900,000 ordinary shares under the Amarin 2002 Stock Option Plan (under which the options were to vest in four equal installments over four years) at an exercise price of $1.35 per share. On November 10, 2010, Thero was granted an option to purchase an additional 1,200,000 ordinary shares under the Amarin 2002 Stock Option Plan (also to vest over four years in equal installments) at an exercise price of $3.40 per share. During 2012, 625,000 of his shares became exercisable and he sold 451,852, or approximately 72% of his total shares available to sell.

378. In sum, from April 9, 2012 through July 27, 2012, Thero sold 451,852 shares of Amarin ADSs for total net proceeds of $4,901,434.

John Thero, President

Sale Date	Shares Sold	Sale Price	Exercise Price	Option Expiration Date	Gross Proceeds	Net Proceeds
4/9/2012	150,926	$9.96	$1.35	12/21/2019	$1,503,072	$1,299,322
7/27/2012	150,926	$14.97	$1.35	12/21/2019	$2,259,362	$2,055,612
7/27/2012	150,000	$13.71	$3.40	11/10/2020	$2,056,500	$1,546,500
FY 2011	**451,852**				**$5,818,934**	**$4,901,434**

379. As with Zakrzewski, there is a discrepancy of approximately 190,537 of the $1.35 options and shares sold between the Form 4s (301,852 options exercised and shares sold) and Amarin's 2014 Proxy Statement at 37 (492,389 of the original 900,000 stock options exercised and sold):

Grant Date	Shares Granted		Exercise Price	Option Expiration Date	Shares held in 2014	Shares Sold		Net Proceeds
12/21/2009	900,000	(1)	$1.35	12/21/2019	407,611	492,389	(3)	$3,354,934
11/11/2010	1,200,000	(2)	$3.40	11/11/2020	750,000	450,000	(3)	$1,546,500

(1) As per F-1 filed 12/14/09.
(2) As per 10-K filed 3/16/11.
(3) This figure is based on the difference between the shares granted column and the shares sold column (which came from the Proxies filed on 5/2/11 and 4/30/14). However, the total shares sold based on Form 4 filings indicate only 301,852 shares have been sold of the $1.35 options and 150,000 of the $3.40 options. The 7/30/12 Form 4 does disclose that 487,037 shares have either been exercised or transferred to Thero's wife per a domestic relations order.

Thero's Form 4 filings only reported 150,000 of the $3.40 options as being exercised and sold, whereas the 2014 Proxy Statement reports that 450,000 of those options were exercised and sold. Thus, Thero may have exercised and sold an additional approximately 490,500 options and shares of Amarin stock than reported on Form 4s.

380. Defendants' sales took place during the period of greatest inflation, when Amarin's stock price rose to a high of $19.50 a share on May 27, 2011. Defendants only ceased selling which Amarin's share fell permanently below $10 a share in December 2012 caused by Amarin's inability to induce a third party to acquire control of Amarin or co-partner in the development of Vascepa. Given the higher strike price of the unexercised options ($3.50 a share), Amarin's lower trading price during 2013, and defendants' need to maintain credibility as Amarin's senior officers at a time Amarin was accessing the public markets in a secondary offering, it is not surprising that defendants exercised *some* restraint against selling *all* their outstanding Amarin common shares.

381. Moreover, in an apparent response to Zakrzewski and Thero's 2011-12 insider sales, in March 2013 Amarin's Board of Directors established a policy that required its senior officers to maintain minimum levels of ownership of Amarin equity. Zakrzewski was required to maintain an equity interest at least equal to three times his base salary of $562,605. Other executive officers were required to maintain an equity interest at least equal to one time their base salary. *See* 2014 Proxy Statement at 32.

382. No inference can be drawn from Ketchum's lack of insider sales. His options first vested in March 2013 at exercise prices of $8.77 and $8.10, and were "out of the money." *See* 2013 Proxy Statement, at 39, fn.3.

383. The Individual Defendants were also motivated to dissemble the truth with respect to the prospects for success of the ANCHOR study to enhance their executive compensation.

384. According to Amarin's 2011 Proxy Statement (at 32) "for 2010, performance-based cash bonuses were determined principally on the Remuneration Committee's overall

subjective assessment of the executive's performance and contribution to the Company's success during the year…." Among the factors considered in the performance-based cash bonus were "creat[ing] an aggressive [Investor Relations strategy and plan" and "[a]chiev[ing] stock price performance that exceeds peer group."

385. In 2010, Zakrzewski was awarded a cash bonus of $100,000 (although he was not a full time employee during that year) and Thero was awarded a cash bonus of $140,000. Also, in 2010, Zakrzewski was awarded 1,750,000 stock options valued at $4,882,500 and Thero was awarded 1,200,000 stock options valued at $3,348,000. Dr. Ketchum was not then employed by Amarin.

386. In 2011, Zakrzewski was awarded a non-equity incentive plan compensation bonus of $159,588 and Thero was awarded a similar bonus of $140,000. Zakrzewski was also awarded 625,000 stock options valued at $4,727,966. Zakrzewski's total compensation in 2011 was $5,196,945. Thero's total compensation was $5,146,630. Dr. Ketchum was not then employed by Amarin.

387. In 2012, Zakrzewski was paid a base salary of $550,000, stock awards valued at $590,667, option awards valued at $2,233,188 and non-equity incentive plan compensation of $305,525, for total compensation of $3,679,380. All told, in 2010 through 2012, Zakrzweski was paid cash and incentive based compensation in excess of $14.0 million, for Amarin's purported success in the MARINE and ANCHOR trials.

388. Thero was paid a base salary in 2012 of $386,300, stock awards valued at $167,454, option awards valued at $632,737, and non-equity incentive plan compensation of $156,065. All told, in 2010 through 2012, Thero was paid cash and incentive based compensation in excess of $5.6 million for his purported success, among other things, in clinical

development and promoting Amarin stock.

389. Ketchum was paid total compensation in 2012 of $4,901,990, consisting of a base salary of $325,000, cash bonus of $31,900, option awards of $4,430,074, and $114,516 in non-equity incentive plan compensation.

390. All three defendants were paid, in the aggregate, from 2010-12, in excess of $24.5 million of executive compensation – an enormous sum considering that the company had hardly any revenue and little to no prospect of success on getting FDA approval for Vascepa based on the ANCHOR indication, without conducting the "bet the ranch" $100 plus million REDUCE-IT test.

C. Defendants Were Motivated to Inflate Amarin's Stock Price and the Misrepresent the Truth in Order to Conduct over $226 Million in Secondary Offerings

391. Significantly, during the Class Period, Amarin conducted two secondary offerings that raised over $226 million – on January 6, 2011 – 18.8 million ADS at $7.60 per ADS, and on July 10, 2013 – 21.7 million ADS at $5.60 per ADS.

392. Without these offerings, Amarin would have lacked the financing to continue the REDUCE-IT study. Defendants knew that investors would have been unwilling to assume the cost, risk and delay of the REDUCE-IT study, and to purchase Amarin shares in the offerings at the prices offered if the true facts concerning the need to successfully complete the REDUCE-IT study had been revealed.

393. Defendants were also motivated to commit the fraud as, during the Class Period, Amarin was actively seeking partners to assist in financing the REDUCE-IT study. Defendants were motivated to not tell the truth concerning their discussions with the FDA to maintain an inflated stock price and negotiate the best possible deal with a third party.

D. Key Senior Employees Left Amarin Soon Before the FDA Ruling on the sNDA for ANCHOR

394. Further giving rise to a strong inference of scienter, two key senior Amarin employees with knowledge of Amarin's communications with the FDA left the Company shortly before the FDA signaled denial and then denied Amarin's sNDA for the ANCHOR indication of Vascepa.

1. Paresh Soni

395. Paresh Soni was Amarin's Senior Vice President and Head of Development from September 2008 – two months after Amarin's July 2008 meeting with the FDA – until the time he left the Company in August 2013.

396. Soni is a board-certified internist and gastroenterologist.

397. According to documents filed as exhibits to Amarin's fiscal 2011 Form 10-K filed with the SEC, Soni reported to the Company's President.

398. As Amarin's Senior Vice President and Head of Development, Soni had access to Amarin's files of communications with the FDA and either knew or if not for his recklessness would have known that the FDA would strongly consider the ACCORD-Lipid, AIM-HIGH and HPS2-Thrive trials in determining whether to approval the ANCHOR trial based only a surrogate endpoint (reducing TGs) without any proof of improved cardiac performance from the REDUCE-IT study. Moreover, Soni knew or was reckless in failing to know in 2012 that the ACCORD-Lipid and AIM-HIGH trials had been unsuccessful, and accordingly it was substantially less likely that Amarin would get approval for the ANCHOR indication.

399. As part of Soni's remuneration, he was granted an option on December 21, 2009 to purchase 800,000 ordinary shares under the Amarin 2002 Stock Option Plan (under which the options were to vest in four equal installments over four years). Between the grant date and

the end of 2011, 400,000 of his shares became exercisable and - notwithstanding Amarin's continual statements of optimism - he sold 200,000, or 50% of his total shares available to sell for net proceeds of $1,957,600.

Paresh Soni, SVP and Head of Development

Sale Date	Shares Sold	Sale Price	Exercise Price	Option Expiration Date	Gross Proceeds	Net Proceeds
2/22/2011	120,000	$8.49	$1.35	12/21/2019	$1,018,800	$856,800
4/19/2011	80,000	$15.11	$1.35	12/21/2019	$1,208,800	$1,100,800
FY 2011	**200,000**				**$2,227,600**	**$1,957,600**

400. Soni sold with knowledge of the true facts concerning the FDA's unwillingness to grant Vascepa approval for the ANCHOR indication based only on a surrogate endpoint and resigned from Amarin in August 2013, prior to the AdCom Hearing, reflecting his lack of confidence in Amarin's ability to get FDA approval of Vascepa for the ANCHOR indication.

2. Paul Huff

401. On February 2, 2011, Amarin announced that "Paul E. Huff has joined the Company as Chief Commercial Officer." According to the press release, "[i]n this role, Mr. Huff is responsible for driving Amarin's Vascepa commercialization strategy, including all marketing and sales planning and implementation, including product launch activities."

402. The press release further stated that Huff "brings more than 25 years of cardiovascular-focused pharmaceutical marking and sales experience to Amarin, with a special emphasis on marketing lipid-modifying prescription pharmaceutics.

403. The press release quoted defendant Zakrzewski as saying, "Paul brings a wealth of industry knowledge and commercialization experience to Amarin that will be invaluable as we work to maximize the commercial value of Vascepa. Paul played a key role in the

commercialization of LOVAZA and Niaspan, two of the most successful lipid products launched in the US market."

404. Amarin's later SEC filings identified Huff as a Senior Vice President, reporting to the President of Amarin. Huff was among the five most senior executives of Amarin, as listed in Amarin's 2011, 2012, and 2013 proxy statements.

405. As Amarin's Chief Commercial Officer and a Senior Vice President, Huff had access to Amarin's files of communications with the FDA and either knew or if not for his recklessness would have known that the FDA would strongly consider the ACCORD-Lipid, AIM-HIGH and HPS2-Thrive trials in determining whether to approval the ANCHOR trial based only a surrogate endpoint (reducing TGs) without any proof of improved cardiac performance from the REDUCE-IT study. Moreover, Huff knew or was reckless in failing to know in 2012 that the ACCORD-Lipid and AIM-HIGH trials had been unsuccessful, and accordingly it was substantially less likely that Amarin would get approval for the ANCHOR indication.

406. As part of Huff's remuneration, he was granted an option on January 28, 2011 to purchase 900,000 ordinary shares under the Amarin 2002 Stock Option Plan (under which the options were to vest in four equal installments over four years). Between the grant date and the end of 2012, 450,000 of his shares became exercisable and he sold 225,000, or 50% of his total shares available to sell.

407. In addition, Huff was granted 41,700 restricted stock units (RSUs) on February 1, 2012 under the Amarin Stock Incentive Plan (under which the RSUs were to vest in six equal installments based on reaching certain drug development milestones). Between the grant date and the end of July 2012, 6,950 RSUs vested and Huff sold 100% of those shares. A Form 4

filed on June 8, 2012 also disclosed that Huff was granted an option on September 4, 2009, to purchase (an unspecified number of) ordinary shares under the Amarin 2002 Stock Option Plan and Huff sold 4,750 shares in June 2012.

Paul Huff, Chief Commercial Officer

Sale Date	Shares Sold	Sale Price	Exercise Price	Option Expiration Date	Gross Proceeds	Net Proceeds
6/7/2012	4,750	$12.06	$1.21	9/4/2019	$57,285	$51,538
6/7/2012	11,975	$12.06	$8.79	1/28/2021	$144,419	$39,158
6/15/2012	100	$12.00	$8.79	1/28/2021	$1,200	$321
6/18/2012	162,925	$12.00	$8.79	1/28/2021	$1,955,100	$522,989
6/26/2012	1,100	$13.52	$8.79	1/28/2021	$14,872	$5,203
6/27/2012	48,900	$15.01	$8.79	1/28/2021	$733,989	$304,158
7/27/2012	541	$14.74	N/A	N/A	$7,974	$7,974
7/27/2012	6,409	$13.78	N/A	N/A	$88,316	$88,316
FY 2012	**236,700**				**$3,003,155**	**$1,019,657**

408. Notwithstanding Amarin's continual statements of optimism, Huff sold based on knowledge of the true facts concerning the FDA's unwillingness to grant Vascepa approval for the ANCHOR indication. Huff resigned from Amarin without public comment in July 2013, prior to the AdCom Hearing, reflecting his significant lack of confidence in Amarin's ability to get FDA approval of Vascepa for the ANCHOR indication based only on a surrogate endpoint.

409. The stock chart on Exhibit A demonstrates that these four insiders grouped the disproportionate amount of their insider sales when Amarin was trading at its highest prices between April 18, 2011 and October 1, 2012.

E. Confidential Witness A Confirmed that Defendants Were Aware of But Chose to Ignore Concerns with the Outcomes Trials

410. Confidential Witness A said from day one he was told by Zakrzewski that Zakrzewski's sole objective was to promote the company with the objective of selling the company for the highest possible price. Confidential Witness A said that he heard that Zakrzewski wanted to sell for $30 a share. Zakrzewski would interview all new hires and told everyone that he wanted to sell the company.

411. Confidential Witness A said that he would meet the Senior Director of Investor Relations and Communications (the "Senior Director") every morning for coffee. They would frequently discuss Zakrzewski's public statements of optimism that ANCHOR would be approved by the FDA without an outcomes study. The Senior Director would tell Confidential Witness A that he tried to get Zakrzewski to be less optimistic in public statements and to recognize the substantial risk that a long term outcomes study could be required prior to approval. Confidential Witness A said that he too discussed Zakrzewski's optimism with Zakrzewski. Confidential Witness A said that he told Zakrzewski to temper his optimism but that Zakrzewski would not listen to anymore. Confidential Witness A said that the Senior Director told Confidential Witness A that the Senior Director was "at the end of his rope." The Senior Director left Amarin in March 2013. Confidential Witness A said that he recommended to Zakrzewski against having information on ANCHOR on Amarin's website.

412. Confidential Witness A also said that he has spoken to two different Medical Science Liaisons (the "MSLs") who worked with Amarin, and specifically defendant Ketchum, in advance of the October 16, 2003 AdCom. The MSLs told Confidential Witness A that defendant Ketchum knew he would receive questioning from the AdCom on the use of mineral oil on placebo and the relevance of ACCORD-LIPID and AIM-HIGH to approving Vascepa for

the ANCHOR indication without an outcomes trial and was concerned that he would be unable to satisfy the FDA's and the AdCom's concerns.

XI. LOSS CAUSATION

413. As detailed herein, Defendants engaged in a course of conduct that artificially inflated the price of Amarin ADS throughout the Class Period. The Defendants' unlawful conduct directly caused the losses incurred by Lead Plaintiff and the other members of the Class. The materially false and misleading statements set forth above were widely disseminated to the securities markets, investment analysts and the investing public. Defendants' materially false and misleading statements artificially inflated the price of Amarin ADS by causing Amarin's ADS price to increase (or not decrease as much as it otherwise would have if Defendants had not made those misstatements).

414. The artificial inflation in Amarin's ADS price was removed when the conditions and facts that had been misstated and omitted by Defendants were revealed to the market. The information was disseminated through a series of corrective disclosures, beginning on July 26, 2012, that revealed the nature and extent of the FDA's warnings to Amarin during the July 2008 meetings regarding the significance to the ANCHOR sNDA of the ACCORD-Lipid and AIM-HIGH study results. These disclosures, more particularly described below, reduced the price of Amarin's publicly traded stock, causing economic injury to Lead Plaintiff and other members of the Class:

(i) On July 26, 2012, in conjunction with its approval of Vascepa for the MARINE indication, the FDA declined Amarin's request to include ANCHOR study results on the Vascepa label, which indicated to investors the possibility that the FDA was less willing to approve Vascepa for the ANCHOR indication solely on the basis of the ANCHOR study. Following this announcement the stock price dropped 11.8% to close the next day at $13.51, down from $15.32 on very high volume of 22.5 million;

(ii) On December 6, 2012, after the market closed, Amarin disclosed to investors that Amarin would not be sold or enter into a joint venture with a larger pharmaceutical company, reflecting that Amarin's future prospects were less bullish than had been represented to investors. On December 7, 2012, Amarin's stock price declined by approximately 18.5% (from $11.95 to $9.69) on extremely reported heavy volume of 19.1 million shares.

(iii) On June 19, 2013, Amarin announced that it was informed by the FDA that the FDA would convene an advisory committee on October 16, 2013 in connection with its review of the sNDA for Vascepa for the ANCHOR indication, which indicated to investors the possibility that the FDA was less willing to approve vascepa for the ANCHOR indication solely on the basis of the ANCHOR study. Amarin shares declined 2.6% (from $6.47 to $6.30) on this news;

(iv) On July 8, 2013, Amarin announced a public offering of 21.7 million ADSs, which indicated to investors concern that the FDA would require Amarin to complete the REDUCE-IT trial prior to approving Vascepa for the ANCHOR indication. Following the offering announcement, Amarin shares declined in price by 9.6% on heavy volume of 11.9 million;

(v) On October 11, 2013, the FDA published its Briefing Document for the October 16, 2013 Advisory Committee Meeting, which summarized the FDA's significant doubt expressed to Amarin in July 2008 that reduction of TGs alone evidenced an improved risk of cardiac issues and stated that based on published test results first available to Amarin in 2010 that there was little indication that a reduction in TGs alone would improve the incidence of cardiac events. This news sent Amarin shares plunging 20.1% (from $6.37 to $5.09) on extremely high volume of 37.9 million shares; and

(vi) On October 16, 2013, the Advisory Committee convened, heard testimony and deliberated on Amarin's sNDA for Vascepa for the ANCHOR indication, resulting in a 9-2 vote to recommend that the FDA reject the sNDA. Trading of Amarin was halted during the meeting, and upon resumption of trading on October 17, 2013, shares declined in price by an additional $3.16 per share (from $5.17 to $2.01) on extraordinary volume of 105.7 million.

415. The timing and magnitude of Amarin's stock price decline negates any inference that the economic losses and damages suffered by Lead Plaintiff and other members of the Class were caused by changed market conditions, macroeconomic factors, or even Company-

specific facts unrelated to Defendants' fraudulent conduct.

XII. APPLICABILITY OF THE PRESUMPTION OF RELIANCE

416. At all relevant times, the market for Amarin's ADSs was an efficient market for the following reasons, among others:

(a) Amarin met the requirements for listing, and was listed and actively traded on the NASDAQ exchange, a highly efficient and automated market;

(b) As a regulated issuer, Amarin filed periodic public reports with the SEC and NASDAQ;

(c) Amarin regularly and publicly communicated with investors via established market communication mechanisms, including through regular disseminations of press releases on the nation circuits of major newswire services and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services; and

(d) Amarin was followed by securities analysts employed by major brokerage firms who wrote reports which were distributed to the sales force and certain customers of their respective firms. These reports were publicly available and entered the public market.

417. As a result of the foregoing, the market for Amarin securities promptly digested current information regarding Amarin from all publicly available sources and reflected such information in the price of Amarin stock. Under these circumstances, all purchasers of Amarin ADSs during the Class Period suffered similar injury through their purchases of Amarin ADSs at artificially inflated prices and the presumption of reliance applies.

418. A class-wide presumption of reliance is also appropriate in this action under the United States Supreme Court holding in *Affiliated Ute. Citizens of Utah v. United States*, 406 U.S. 128 (1972) because the claims asserted herein against Defendants are predicated upon omissions of material fact which there is a duty to disclose.

XIII. THE INAPPLICABILITY OF THE STATUTORY SAFE HARBOR

419. Substantially all Defendants' statements alleged herein to be materially false and

misleading are statements of existing fact to which the statutory safe harbor is not applicable.

420. Amarin's generic "safe harbor" warnings accompanying any forward-looking statements issued during the Class Period are in any event ineffective to shield those statements from liability.

421. Although Amarin routinely identified to investors certain generic risks that Amarin could be subjected to, it failed to disclose to investors the meaningful cautionary facts, risks, and statements known to Defendants with respect to the FDA's stated position on the implications of ACCORD-Lipid, AIM-HIGH and other outcomes studies on Amarin's ANCHOR sNDA; the concerns expressed internally at Amarin and by the FDA that mineral oil was not inert; and that the JELIS test results could not be considered predictive of the REDUCE-IT study or supportive of the efficacy of Vascepa for the ANCHOR indication.

422. Defendants are liable for any false or misleading forward-looking statements pleaded herein because, at the time each such statement was made, the speaker knew the statement was false or misleading and the statement was authorized and/or approved by an executive officer of Amarin who knew that the statement was false.

XIV. CLAIMS FOR RELIEF

COUNT 1

Against Defendants for Violation of Sections 10(b) of The Exchange Act and Rule 10b-5 Thereunder

423. Plaintiff incorporates each of the foregoing paragraphs as if fully set forth herein.

424. Defendants participated in a course of conduct involving misrepresentation and concealment of adverse material information about the business of Amarin as specified herein.

425. Defendants employed devices, schemes and artifices to defraud, while in possession of material adverse non-public information and engaged in acts, practices, and a

course of fraudulent conduct as alleged herein in an effort to assure investors of Amarin's progress, which included the making of, or the participation in the making of, untrue statements of material facts and omitting to state material facts necessary in order to make the statement made about Amarin and its business, in light of the circumstances under which they were made, not misleading. This conduct operated as a fraud and deceit upon the purchasers of Amarin securities during the Class Period.

426. The Individual Defendants are liable as direct participants in the wrongs complained of herein. With knowledge of the falsity of the statements contained therein and in the reckless disregard of the true status of the FDA analysis of Vascepa, the Individual Defendants caused the complained of misstatements and omissions of material fact as alleged herein, and knowingly or recklessly failed in their duties to update or correct misleading statements issued by them or on their behalf.

427. Since joining Amarin, the Individual Defendants had actual knowledge of the misrepresentations and omissions of material fact set forth herein, or acted with reckless disregard for the truth in that they failed to ascertain and disclose such facts, even though such facts were available to them.

428. Had Plaintiff and the other members of the Class known of the material adverse information not disclosed by Defendants, or had they been aware of Defendants' material misstatements, they would not have purchased Amarin's securities at artificially inflated prices.

429. Plaintiff and the Class were injured because the risks that materialized were risks of which they were unaware as a result of Defendants' misrepresentations, omissions and other fraudulent conduct alleged herein. The decline in the price of Amarin's securities was caused by the public dissemination of the true facts, which were previously concealed or hidden.

Absent Defendants' wrongful conduct, plaintiffs and the Class would not have been injured.

430. The price of Amarin securities declined materially upon public disclosure of the true facts which had been misrepresented or concealed, as alleged in this complaint. Plaintiff and other members of the Class have suffered substantial damages as a result of the wrongs alleged herein.

431. By reason of the foregoing, Defendants violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

COUNT II

Against Individual Defendants
Pursuant to Section 20(a) of the Exchange Act

432. Plaintiff incorporates by reference and realleges each of the foregoing allegations.

433. The Individual Defendants had direct involvement in the day-to-day operations of the Company and had the power to control or influence the particular statements giving rise to the securities violations as alleged herein, and exercised the same.

434. As set forth above in Count I, Amarin violated Section 10(b) and Rule 10b-5 promulgated thereunder by its acts and omissions as alleged in this Complaint.

435. By virtue of his position as Chairman and Chief Executive Officer of Amarin, Defendant Zakrzewski is liable for the company's violations of Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder, as alleged in Count I, pursuant to Section 20(a) of the Exchange Act.

436. By virtue of his position as President and Chief Financial Officer of Amarin, Defendant Thero is liable for the company's violations of Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder, as alleged in Count I, pursuant to Section 20(a) of the

Exchange Act.

437. By virtue of his position as Senior Vice President and President of Research and Development of Amarin, Defendant Ketchum is liable for the company's violations of Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder, as alleged in Count I, pursuant to Section 20(a) of the Exchange Act.

438. As a result of the deceptive practices and false and misleading statements and omissions, the market price of Amarin's ADSs was artificially inflated during the Class Period. In ignorance of the false and misleading nature of the representations described above and the deceptive and manipulative devices employed by Defendants, Plaintiff and the other members of the Class, in reliance on either the integrity of the market and/or directly on the statements and reports of Defendants, purchased Amarin's ADSs at artificially inflated prices.

439. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and other members of the Class suffered damages in connection with their purchases of the Company's securities during the Class Period.

440. By virtue of the foregoing, Individual Defendants violated Section 20(a) of the Exchange Act.

441. Plaintiff and the other members of the Class have been damaged by the violations as described in this Count and seek recovery for the damages caused thereby.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, on behalf of himself and the other members of the Class, prays for judgment as follows:

1. Declaring this action to be a proper class action maintainable pursuant to Rule 23(b)(3) of the Fed.R.Civ.P. and declaring Plaintiff to be a proper Class representative;

2. Awarding Plaintiff and the other members of the Class damages suffered as a result of the wrongs complained of herein, together with appropriate interest;

3. Awarding Plaintiff and the other members of the Class their costs and expenses of this litigation, including reasonable attorneys' fees and experts' fees and other costs and disbursements; and

4. Awarding Plaintiff and the other members of the Class such other and further relief as may be just and proper under the circumstances.

JURY DEMAND

Plaintiff demands a trial by jury for all claims so triable.

Dated: July 29, 2015

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In re Amarin Corporation PLC, Securities Litigation

Civil Action No. 13-cv-0663

Second Consolidated and Amended Class Action Complaint

Exhibit A

Dated: July 29, 2015

SECOND CONSOLIDATED AND AMENDED CLASS ACTION COMPLAINT, DATED JULY 29, 2015, EXHIBIT A